

UNITED STATES DISTRICT COURT FOR
THE DISTRICT OF NEW JERSEY

CHRISTINE JANKOWSKI, Personal Representative of the Estate of JOHN JANKOWSKI; KIRK ALBRECHT; HEIDI ALBRECHT; PATSY ALDRED; PAUL ALDRED; JOHN ALEXANDER; DON AMBURGEY; JOYCE AMBURGEY; MAX AUSTIN; CHRISTINE AUSTIN; MARVIN BAUMAN; ROWENA BAUMAN; TY BEARD; TOM BELL; NANCY BELL; MARY BLEVINS, Personal Representative of the Estate of MICHAEL BLEVINS; RALPH BOOTH; BETTY BOSTIC; JIMMY BOSTIC; TIMOTHY BRAWLEY; SUSAN BRAWLEY; SHIRLEY BRINKLEY; JACK BRINKLEY; TIFFANY BROOKS, Personal Representative of the Estate of MINNIE DARISAW; LINDA BRUNNER; FRED BURROUGH; SONJA BUTLER, Personal Representative of the Estate of RAYMOND BUTLER; JAMES D. CALVIN; HELEN CALVIN; DELBERT CARTER; BOBBIE CARTER; KARMEN CARUSO; RANIERE CASERTA; COUCHITA CASERTA; JOHN CHAPMAN, SR.; LOIS CHILDS; NOEL CLECKLER; FRANCES CLECKLER; JO ANN COLLINGS, Personal Representative of the Estate of ROBERT COLLINGS; KENNETH COLLINS; KIM COLLINS; RACHEL COOK; JENNITH COONTZ; DONALD COONTZ; MARY COX; MARY DAVIS; VERNON DEBOARD, Personal Representative of the Estate of KATHERINE DEBOARD; SUSAN FEDORSHA, Personal Representative of the Estate of JOSEPH FEDORSHA; CHARLES FENDLEY; PATRICIA FENDLEY; ANDREW FANCHER, Personal Representative of the Estate of JULIANNE WINTKER; DIANE ZAREMBO; MICAH GARTMAN; PAMELA GIBSON; RUTH GLASCOE, Personal Representative of the Estate of WILLIAM GLASCOE; BARBARA GRANTHAM, Personal Representative of the Estate of LARRY GRANTHAM; FRANCIS GROMADZKI; LEE ANN GROMADZKI; CAROLYN HALE, Personal Representative of) Case No.: No. 1:20-cv-02458) SECOND AMENDED COMPLAINT FOR:) STRICT PRODUCTS LIABILITY –) FAILURE TO WARN;) NEGLIGENCE – FAILURE TO WARN) JURY TRIAL DEMANDED

the Estate of BENNY HALE; EUGENE)
HAMILTON; JOANN HAMILTON; SHIRLEY)
HART; DEBORAH HENSLEY; HENRY)
HENSON, Personal Representative of the Estate)
of JANE HENSON; REX HESS; DELBERT)
HINKLE; SARA HUFF, Personal Representative)
of the Estate of MILDRED CAGLE; CLINTON)
HUMPHREY; TENNA HUMPHREY; BRAHA)
JACKSON; DORIS JOHNSON; MICHAEL)
JOHNSTON, Personal Representative of the)
Estate of PATRICIA JOHNSON; PINK JONES;)
ANNIE JONES; STEPHANIE KIBODEAUX,)
Personal Representative of the Estate of LATUIS)
KIBODEAUX; BARBARA KING; SAMUEL)
KING; DENNIS KOCH; BARBARA KOCH;)
MARK LAGANELLI, Personal Representative of)
the Estate of LAWRENCE LAGANELLI;)
BEVERLY LANDRUM, Personal Representative)
of the Estate of JOHN LANDRUM, JR.; DANIEL)
LEONG; LAURAN LEONG; FRANCIS)
LOMBARDI; ANGELA LOMBARDI; NANCY)
LOVVORN, Personal Representative of the)
Estate of FRANK LOVVORN; KIM LEE LOWE,)
Personal Representative of the Estate of JOANN)
LOWE; BERNICE MANZO; ROBERT MASON;)
GLENDY McGUFFIE; BRENDA MEDLER,)
Personal Representative of the Estate of ROBERT)
MEDLER; GEORGE MILLER; JOHN L.)
MORRIS; ELIZABETH MORRIS; LONNIE)
MYERS; BARBARA MYERS; HANS)
OMASTA; WINONA OMASTA; ROBERT)
PERKINS; LISA PULLEN; RICHARD REED;)
VICKI REED; SANDRA RHODES; CHARLES)
RHODES; BOBBIE ROBERTS; TROY)
ROBERTS; LARRY E. ROBINSON; LOIS)
RONCAL; JIMMIE ROSS; KAREN ROTH,)
Personal Representative of the Estate of DORIS)
HILDEBRAND; RICHARD RYAN;)
MOHAMMAD SALEEM; ALBERT)
SHEPHERD, Personal Representative of the)
Estate of EMILY SHEPHERD; CYNTHIA)
SKILES; RAYMOND SKILES; JEANETTE)
SMITH-AKYOL; IEDA STURGILL; BRIAN)
SUKENIK; GEORGIA SUTTON; WILLIAM)
TEESCH; CECIL THOMAS; DEBBIE)
THOMAS; JOHN NATHAN TIMM; LAUREL)
TURLEY; ROGER TURLEY; DOYLE)
TURNER, Personal Representative of the Estate)

of CAROLYN TURNER; JANICE UPTON,)
Personal Representative of the Estate of JANICE)
COVINGTON; MARTHA VERNON; GEORGE)
VIOLA; MARY WATERS; STEWART)
WILKINS; MARY WILKINS; NANCY)
WILLIAMS; JIM WILLIAMS; KATHERINE)
WOLLASTON; DANIEL WOLLASTON;)
JAMES MASON; CATHY MASON;)
JACQUELINE FABBRI, Personal Representative)
of the Estate of FRANK FABBRI; ROBERT)
KIZANIS; VELOMY KIZANIS; CARLETTA)
WILLIAMS, Personal Representative of the)
Estate of JAMES C. WILLIAMS, III; ELMO)
WAYNE DUNCAN; JOHN BLACKFORD;)
MAXINE BLACKFORD; DARLENE)
GLASGOW, Personal Representative of the)
Estate of KENNETH GLASGOW; DIANNE)
CRUCE; DOUG HYAK; BILL)
WORTHINGTON, Personal Representative of the)
Estate of BETTYE WORTHINGTON;)
BIRGITTA BENGTSSON; VERONICA ITANO,)
Personal Representative of the Estate of PHILLIP)
ITANO; DIANE MANCINELLI; JAMES)
VINSON, JR.; ROBERT E. SMITH; AMY)
MILLER, Personal Representative of the Estate of)
LARRY MILLER; DORIS LYLE, Personal)
Representative of the Estate of JAMES LYLE;)
DAVID WAYNE GORBETT; NORMA)
GORBETT; ROBERT GHISELIN; GERI)
GHISELIN; GEORGE L. BUSH; EDWIN)
MARTIN; BRENDA BAREFOOT, Personal)
Representative of the Estate of CLARK)
BAREFOOT; MARY PARKER; DON ASH;)
JANNA ASH; IMOGENE BERRY; FRANCIS)
DODD; THERESA GRAVES, Personal)
Representative of the Estate of ROBERT)
GRAVES; ANN MORISEY AND CHARLES)
MORISEY; HARSHARAN SANDHU, Personal)
Representative of the Estate of GURDIP)
SANDHU; JOHN HENDRIX; LINDA PERRY;)
JAMES JORDAN; SHARON JORDAN;)
CHARLES PRICE; JAMES ROADCAP, SR.;)
EDNA ROADCAP; PATRICIA SOPP, Personal)
Representative of the Estate of PHILIP SOPP;)
BARBARA CLARK, Personal Representative of)
the Estate of ROY L. CLARK; KRIKOR)
PECHAKJIAN; DEBRA LISTER, Personal)
Representative of the Estate of MARK)

ANTHONY; RAYMOND WRIGHT, Personal Representative of the Estate of SARIANNE WRIGHT; JACQLYN CARTER, Personal Representative of the Estate of JACK CARTER; MARSHA McCRORY; CARLA ELLIS, Personal Representative of the Estate of IVA WALKER; NANCY BARBER, Personal Representative of the Estate of JOHN GLYNNE BARBER; RITA PENNINGTON; ROBERTA SCHROEDER; CARL SCHROEDER; LOYCE PARR, Personal Representative of the Estate of DELMAS PARR; PATRICIA RHODES, Personal Representative of the Estate of REX RHODES; JAMES THOMAS, Personal Representative of the Estate of SYBLE THOMAS; DIANA CUTRIGHT, Personal Representative of the Estate of RICHARD CUTRIGHT; JERRY COSS; BRENDA COSS; ANDREA MILLER (Personal Representative of the Estate of CHARLES MILLER); DIANE DESMOND (Personal Representative of the Estate of PHILIP SCHUB); BRUCE WEHLING (Personal Representative of the Estate of LEONARD WEHLING, JR.); ROY BLAKE (Personal Representative of the Estate of VIRGINIA WEIDER); CLAUDIA CAFFERATTA (Personal Representative of the Estate of JOSE NEME); ROGER BOLIN; SHERRY BOLIN; DON DELLERT (Personal Representative of the Estate of MARILYN DELLERT);

Plaintiffs

v.

ZYDUS PHARMACEUTICALS USA, INC.; and DOES 1-50, Inclusive,

Defendants,

The Plaintiffs listed above (collectively referred to throughout this Second Amended Complaint as "Plaintiffs" unless otherwise indicated), by and through Plaintiffs' attorneys listed below for Plaintiffs' Second Amended Complaint and Demand for jury Trial against Defendants ZYDUS PHARMACEUTICALS USA, INC., and DOES 1-50, inclusive (collectively referred to

throughout this Second Amended Complaint as “Defendants”, “Zydus” unless otherwise indicated), allege as follows¹:

PARTIES, JURISDICTION, AND VENUE

1. Plaintiff Christine Jankowski

- a) On personal knowledge, Plaintiff Christine Jankowski, Personal Representative of the Estate of John Jankowski, deceased, (hereinafter “Plaintiff” or “Jankowski”) is an individual who resides in Ocean County, New Jersey. Mr. Jankowski was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In July 2017, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.
- b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.
- c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed

¹ The allegations as to the individual Plaintiffs are based on the individual personal knowledge of the individual Plaintiffs listed below. Other allegations are on information and belief, which facts are likely to have evidentiary support after a reasonable opportunity for investigation and discovery.

Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around July 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. John Merlino prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. John Merlino was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Merlino did not receive FDA warnings from Defendant.

e) Dr. Merlino was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately November 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, chest pain, weakness, and dizziness. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Mr. Jankowski was a healthy and active individual. After developing pulmonary fibrosis, he struggled to exert himself, was very weak and went into respiratory failure. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) After developing pulmonary fibrosis, his condition deteriorated rapidly. He could not adequately breathe on his own and his condition worsened. John Jankowski succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on October 20, 2018.

2. Plaintiffs Kirk Albrecht and Heidi Albrecht

a) On personal knowledge, Plaintiff Kirk Albrecht (hereinafter "Plaintiff" or "Albrecht") is an individual who resides in Williamson County, Texas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced thyroid disease, pulmonary toxicity and vision loss, all life-threatening and debilitating conditions. In or around January 2016, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced lung toxicity, thyroid toxicity and hyperthyroidism, as well as vision loss. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe

and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In January 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Clay Cauthen and Dr. Haeussein Schumaker prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Clay Cauthen and Dr. Haeussein Schumaker were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Cauthen and Dr. Schumaker did not receive FDA warnings from Defendant.

e) Dr. Cauthen and Dr. Schumaker were not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately May 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, fatigue, chest pain, edema, tremors, weakness, blurred vision, vision loss, deposits within the eye, memory loss, headaches, trouble sleeping, irregular heart rate and migraines. He was presented with a diagnosis of Amiodarone-induced pulmonary disease, hyperthyroidism and vision loss. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly. In addition to pulmonary disease, he was also diagnosed with Amiodarone-induced thyroid toxicity, vision loss and hyperthyroidism.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary disease, thyroid disease and vision loss, Plaintiff was a healthy and active individual. After developing pulmonary injury, thyroid disease and vision loss, he now struggles to exert himself and keep up with the daily activities of life. He also has struggles with weight fluctuations and from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary, vision and thyroid injuries.

i) Additionally, Plaintiff Heidi Albrecht is the spouse of the Plaintiff Kirk Albrecht, and resides with her spouse, and she depended on Kirk Albrecht to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Kirk Albrecht, Plaintiff Heidi Albrecht has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical

care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

3. **Plaintiffs Patsy Aldred and Paul Aldred**

a) On personal knowledge, Plaintiff Patsy Aldred (hereinafter “Plaintiff” or “Aldred”) is an individual who resides in Henrico County, Virginia. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and vision complications, life-altering and debilitating conditions. In or around October 2009, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed vision loss and other vision complications from Amiodarone toxicity. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In October 2009, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warngins, Dr. Stephen Cross prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Stephen Cross was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Cross did not receive FDA warnings from Defendant.

e) Dr. Stephen Cross was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and her prescription was for an "off-label" use.

f) Beginning in approximately December 2015, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include vision loss, multiple vision complications, blood clots, bleeding abnormalities, abnormal heart rhythm and fatigue. She was presented with several diagnoses related to her vision loss, including a macular hole, vitreomacular adhesions, cataracts, pseudophakia, glaucoma and retinal proglems. These visual conditions are debilitating, chronic, progressive conditions that only worsen over time and make it difficult to see and keep up with activities of daily life.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale

of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing vision loss and multiple vision complications, she was a remarkably healthy and active individual. After developing vision loss, she could not see well and struggled to perform necessary activities of daily life. She also suffers from a litany of other health problems related to her use of Amiodarone.

i) Additionally, Plaintiff, Paul Aldred, is the spouse of the Plaintiff Patsy Aldred, and resides with his spouse, and he depended on Patsy Aldred to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Patsy Aldred, Plaintiff Paul Aldred has in the past and will in the future suffer and incur loss of her consortium, loss of his spouse's services, the cost and expense of having medical care, attention and treatment for his spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for her.

4. **Plaintiff John Alexander**

a) On personal knowledge, Plaintiff John Alexander (hereinafter "Plaintiff" or "Alexander") is an individual who resides in Tarrant County, Texas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed vision loss from Amiodarone toxicity, a life-altering and debilitating condition. In or around September 2013, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed vision loss from Amiodarone. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe

and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In September 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. David Parrish, Jr. prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. David Parrish, Jr. was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Parrish did not receive FDA warnings from Defendant.

e) Dr. Parrish was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately 2014, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include loss of vision, floaters, irritated and dry

eyes, itchy eyes, constant eye watering, decline in visual acuity, trouble with coordination due to vision loss, and cataracts. He was presented with a diagnosis of Amiodarone-induced vision injury and loss including corneal deposits and cataracts in both eyes. Amiodarone-induced vision injury and loss is a debilitating condition that worsens over time, resulting in other visual complications. Amiodarone-induced vision loss/injury often cannot be corrected and causes a significant impairment on quality of life.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone toxicity, he was a remarkably healthy and active individual. After developing Amiodarone-induced vision loss/injury, he could not easily read or drive. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced vision loss/injury.

5. Plaintiffs Don Amburgey and Joyce Amburgey

a) On personal knowledge, Plaintiff Don Amburgey (hereinafter "Plaintiff" or "Amburgey") is an individual who resides in Letcher County, Kentucky. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendant and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease, vision injury, kidney disease and abnormal thyroid function, all life-threatening and debilitating conditions. In or around January 2009, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced interstitial lung disease, vision loss and impairment, kidney disease, and hypothyroidism. He received no warning from his physician about these potential life-

threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In June 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Arun Rao prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Arun Rao was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Rao did not receive FDA warnings from Defendant.

e) Dr. Rao was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its

bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately August 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, coughing, fatigue, weakness, cataracts, blurred vision, eye pain, vision loss, depression, anxiety, dizziness, weight loss, kidney and thyroid disease. He was presented with a diagnosis of Amiodarone-induced interstitial lung disease, vision injury, kidney disease, and hypothyroidism. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced interstitial lung disease is extremely poor. Amiodarone-induced interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced interstitial lung disease, vision loss, pulmonary, kidney, and thyroid disease, Plaintiff was a remarkably healthy and active individual. After developing these disabling injuries, he struggles to exert himself, cannot leave his home, requires assistance for all daily living activities, and has become depressed. He also lost weight and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced injuries.

i) Additionally, Plaintiff Joyce Amburgey is the spouse of the Plaintiff Don Amburgey, and resides with her spouse, and she depended on Don Amburgey to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Don Amburgey, Plaintiff Joyce Amburgey has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse’s services, the cost and expense of having

medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

6. **Plaintiffs Max Austin and Christine Austin**

a) On personal knowledge, Plaintiff Max Austin (hereinafter “Plaintiff” or “Austin”) is an individual who resides in Clarke County, Georgia. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed pulmonary fibrosis, which is a life-threatening and debilitating condition. In or around December 2016, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed pulmonary fibrosis and Amiodarone-induced lung toxicity, both serious and potentially deadly complications. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around December 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA

warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Catherine Marti prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Catherine Marti was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Marti did not receive FDA warnings from Defendant.

e) Dr. Marti was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately July 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, coughing, wheezing, trouble breathing, fatigue, chest pain and weakness. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Amiodarone-induced pulmonary fibrosis is a debilitating, chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after his diagnosis that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing pulmonary fibrosis and Amiodarone-induced lung toxicity, he was a remarkably healthy and active individual. After developing pulmonary fibrosis, he struggles to exert himself and to enjoy the things he once did. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) Additionally, Plaintiff, Christine Austin is the spouse of the Plaintiff Max Austin, and resides with her spouse, and she depended on Max Austin to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Max Austin, Plaintiff Christine Austin has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

7. **Plaintiffs Marvin Bauman and Rowena Bauman**

a) On personal information, Plaintiff, Marvin Bauman (hereinafter "Plaintiff" or "Bauman") is an individual who resides in Laurel County, Kentucky. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In December 2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative

to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In December 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Marwan Mihyu prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Chalhoub was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Mihyu did not receive FDA warnings from Defendant.

e) Dr. Mihyu was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately July 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, extreme fatigue, dizziness, sleep apnea and edema. He was presented with a diagnosis of pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time.

The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing pulmonary fibrosis, he was a remarkably healthy and active individual. After developing pulmonary fibrosis, he became extremely weak and became short of breath walking across the room. He developed sleep apnea and edema and he suffers from a litany of other health problems apparently related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) Additionally, Plaintiff, Rowena Bauman is the spouse of the Plaintiff Marvin Bauman, and resides with her spouse, and she depended on Plaintiff, Marvin Bauman to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff, Marvin Bauman, Plaintiff, Rowena Bauman has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

8. **Plaintiff Ty Beard**

a) On personal knowledge, Plaintiff Ty Beard (hereinafter "Plaintiff" or "Beard") is an individual who resides in Travis County, Texas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision injury and loss, a life-altering and debilitating condition. In or around June 2015, he was diagnosed as suffering from atrial fibrillation, which is

a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced vision injury and loss, a serious and potentially disabling condition. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In July 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Samuel DeMaio prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Samuel DeMaio was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe

Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. DeMaio did not receive FDA warnings from Defendant.

e) Dr. De Maio was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately December 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include vision loss and partial blindness, total loss of peripheral vision, light sensitivity, poor coordination due to vision loss, shortness of breath on exertion and fatigue. He was presented with a diagnosis of Amiodarone-induced loss and partial blindness in both eyes. Amiodarone-induced vision loss is a debilitating condition that could worsen over time resulting in other visual complications including but not limited to eye pain, irritation, floaters, retinal detachment, corneal disease, optic neuropathy, cataracts, and Amiodarone deposits within the eye. Amiodarone-induced vision loss often cannot be corrected and results significant limitations and impairment on quality of life.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced vision loss and partial blindness, Plaintiff was a remarkably healthy and active individual. He enjoyed spending time with his family and working. After developing vision loss, he struggles to enjoy regular activities such as reading, driving and watching television, and often requires assistance. He also and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat her Amiodarone-induced vision loss.

9. **Plaintiffs Tom Bell and Nancy Bell**

a) On personal information, Plaintiff, Tom Bell (hereinafter “Plaintiff” or “Bell”) is an individual who resides in Chaffee County, Colorado. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary lung toxicity, a life-threatening and debilitating condition. In February 2013, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In July 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Funsalida prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone

manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Funsalida was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Funsalida did not receive FDA warnings from Defendant.

e) Dr. Funsalida was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) In approximately August 2016, he began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, fatigue, chest pain, weakness, itching and abnormal heart rate. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. The survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing pulmonary fibrosis, he was a remarkably healthy and active individual. After developing pulmonary fibrosis, he struggles to exert himself and to enjoy the

things he once did. He also suffers from a litany of other health problems apparently related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary disease.

i) Additionally, Plaintiff, Nancy Bell is the spouse of the Plaintiff Tom Bell, and resides with her spouse, and she depended on Plaintiff, Tom Bell to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff, Tom Bell, Plaintiff, Nancy Bell has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

10. **Plaintiff Mary Blevins**

a) On personal knowledge, Plaintiff Mary Blevins, Personal Representative of the Estate of Michael Blevins, deceased, (hereinafter "Plaintiff" or "Blevins") is an individual who resides in Hartford County, Maryland. Mr. Blevins was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, respiratory failure and kidney disease, life-threatening and debilitating conditions. In June 2016, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a "rhythm medication," which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor

receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around June 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Reed Riley prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Reed Riley was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Riley did not receive FDA warnings from Defendant.

e) Dr. Riley was not aware that Plaintiff’s use of the medication was for an “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately August 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, abnormal kidney function, fatigue, weakness and vision loss. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis, kidney disease and

respiratory failure. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Mr. Blevins was a healthy and active individual. After developing pulmonary fibrosis, he could not walk across the room and suffered frequent pneumonias. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) After developing pulmonary fibrosis, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring breathing assistance and oxygen use. After being admitted to the hospital, Michael Blevins succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on August 23, 2016.

11. **Plaintiff Ralph L. Booth**

a) On personal knowledge, Plaintiff, Ralph Booth (hereinafter "Plaintiff" or "Booth") is an individual who resides in Suffolk County, Virginia. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced lung disease, a life-threatening and debilitating condition. In December, 2013, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-

threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In December 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Bhavdeep Gupta prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Bhavdeep Gupta was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Gupta did not receive FDA warnings from Defendant.

e) Dr. Gupta was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its

bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately January 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, coughing, exhaustion and overall weakness. He went to the hospital and a high definition CT scan was performed. The CT scan confirmed he had severe lung damage and Amiodarone toxicity. He was also diagnosed with anemia with renal failure. His severe lung condition worsened and even on oxygen he was still unable to breathe easily. His cardiologist stopped his Amiodarone and began a course of treatment of prednisone and bactrim.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone toxicity and renal failure, he was a remarkably healthy and active individual. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced lung disease.

12. **Plaintiffs Betty Bostic and Jimmy Bostic**

a) On personal knowledge, Plaintiff Betty Bostic (hereinafter “Plaintiff” or “Bostic”) is an individual who resides in Pulaski County, Arizona. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injury, severe and debilitating vision condition. In approximately January 2013, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary injury and vision loss, both serious and debilitating diseases. She received no warning from her physician

about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around January 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Jeffrey Dell prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Jeffrey Dell was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Dell did not receive FDA warnings from Defendant.

e) Dr. Dell was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately July 2015, she began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, difficulty breathing, coughing, fatigue, weakness, vision loss, blurry vision, confusion, hair loss, weight fluctuations, anemia, and abnormal bleeding. She was presented with a diagnosis of Amiodarone-induced pulmonary disease and vision loss. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary injury is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary disease and vision loss, Plaintiff was a remarkably healthy and active person who enjoyed spending time with her family. After developing Amiodarone-induced pulmonary disease and vision loss, she struggles to perform daily living tasks independently, and struggles exert herself, and she struggles to read, watch television, and drive. Her vision and pulmonary injuries have significantly impacted the quality of her life. She also gained weight and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary and vision injuries.

i) Additionally, Plaintiff Jimmy Bostic, is the spouse of the Plaintiff Betty Bostic, and resides with his spouse, and he depended on Betty Bostic to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Betty Bostic, Plaintiff Jimmy Bostic has in the past and will in the future suffer and incur loss of her consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

13. **Plaintiffs Timothy Brawley and Susan Brawley**

a) On personal knowledge, Plaintiff Timothy Brawley (hereinafter "Plaintiff" or "Brawley") is an individual who resides in Crow Wing County, Minnesota. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision injury and partial blindness, a life-altering and debilitating condition. In or around June 2016, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced optic neuropathy resulting in ischemic optic neuropathy causing vision loss and blindness. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In June 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Chuen Tang prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Chuen Tang was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Tang did not receive FDA warnings from Defendant.

e) Dr. Tang was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately October 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include vision loss, eye pain, visual disturbances, eye dryness and burning, headaches, dizziness, and poor coordination due to loss of vision. He was presented with a diagnosis of Amiodarone-induced ischemic optic neuropathy resulting in vision loss and partial blindness. Amiodarone-induced ischemic optic neuropathy

damage and blindness is a debilitating, chronic, progressive condition that does not improve over time resulting in significant disability and impaired quality of life

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced ischemic optic neuropathy resulting in blindness, plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced blindness, he can no longer read or drive and requires assistance with daily life activities. He also suffers from a litany of other health problems related to his use of Amiodarone.

i) Additionally, Plaintiff, Susan Brawley, is the spouse of the Plaintiff Timothy Brawley, and resides with her spouse, and she depended on Timothy Brawley to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Timothy Brawley, Plaintiff Susan Brawley has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

14. **Plaintiffs Shirley Brinkley and Jack Brinkley**

a) On personal knowledge, Plaintiff Shirley Brinkley (hereinafter "Plaintiff" or "Brinkley") is an individual who resides in Marion County, Illinois. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and vision complications, life-altering and debilitating conditions. In or around December 2016, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which

turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed vision loss and other vision complications from Amiodarone toxicity. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In approximately January 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Ibrahim prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Ibrahim was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Ibrahim did not receive FDA warnings from Defendant.

e) Dr. Ibrahim was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and her prescription was for an "off-label" use.

f) Beginning in approximately December 2017, she began to experience many of the symptoms outlined in the FDA labeling, which include vision loss and peripheral vision loss, eye discomfort, floaters and poor coordination due to vision loss. She was presented with a diagnosis of Amiodarone-induced vision loss and optic nerve damage. Amiodarone-induced vision loss is a debilitating, chronic, progressive condition that only worsens over time. The recovery rate for individuals with Amiodarone-induced ischemic optic neuropathy is extremely poor.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced ischemic optic neuropathy and total vision loss, plaintiff was a remarkably healthy and active individual. After developing vision loss, she could not read or drive and often requires assistance with daily life activities. She also suffers from a litany of other health problems related to her use of Amiodarone.

i) Additionally, Plaintiff, Jack Brinkley, is the spouse of the Plaintiff Shirley Brinkley, and resides with his spouse, and he depended on Shirley Brinkley to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Shirley Brinkley, Plaintiff Jack Brinkley has in the past and will in the future suffer and incur loss of her consortium, loss of his spouse's services, the cost and expense of having medical care, attention and treatment for his spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for her.

15. **Plaintiff Tiffany Brooks**

a) On personal knowledge, Plaintiff Tiffany Brooks, Personal Representative of the Estate of Minnie Darisaw, deceased, (hereinafter “Plaintiff” or “Darisaw”) is an individual who resides in Jefferson County, Georgia. Minnie Darisaw was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injury, kidney disease, and vision loss, all life-threatening and debilitating conditions. In August 2013, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. Her cardiologist prescribed her a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary injury, a serious and potentially deadly lung disease, vision loss and kidney disease. She received no warning from her physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around August 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below,

along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. David Clark prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. David Clark was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Clark did not receive FDA warnings from Defendant.

e) Dr. Clark was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, vision loss, dizziness, and worsened kidney disease. She was presented with a diagnosis of Amiodarone-induced pulmonary injury, vision loss and kidney disease. Amiodarone-induced pulmonary injury is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale

of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary injury, kidney disease, and vision loss, Minnie Darisaw was a healthy and active individual. After developing pulmonary injury, kidney disease and vision loss, she could not exert herself or keep up with daily life activities. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary injury including vision loss and kidney failure.

i) After developing Amiodarone-induced pulmonary injury, vision loss and kidney failure her condition deteriorated rapidly. She could not adequately breathe and became weaker, and her kidneys began to fail. After spending several days in the hospital, Minnie Darisaw succumbed to her Amiodarone-induced injuries and renal failure on September 15, 2016.

16. **Plaintiff Linda Brunner**

a) On personal knowledge, Plaintiff Linda Brunner (hereinafter “Plaintiff” or “Brunner”) is an individual who resides in Butler County, Ohio. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss/injury, a life-altering and debilitating condition. In or around June 2015, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced vision loss and injury, a serious and potentially disabling condition. She received no warning from her physician about these potential debilitating complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her

doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone, more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In or around June 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. George S. George prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. George S. George was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. George did not receive FDA warnings from Defendant.

e) Dr. George was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately April 2016, she began to experience many of the symptoms outlined in the FDA labeling, which include vision loss and difficulty seeing as a result of the Amiodarone-induced corneal deposits within her eyes, trouble with coordination due to

vision loss, floaters, decreased visual acuity, and increased anxiety. She was presented with a diagnosis of Amiodarone-induced epithelial corneal deposits, astigmatism and presbyopia. Amiodarone-induced vision injury is debilitating and is known to worsen over time and may result in other visual complications including but not limited to, eye pain, irritation, floaters, corneal disease, loss of visual acuity and peripheral vision, deposits within the eye, and cataracts.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing vision injury, Plaintiff was a remarkably healthy and active individual. After developing vision injury, she could not easily read or drive or continue working. Amiodarone-induced vision injury and vision loss has resulted in significant impairment on her quality of life.

17. **Plaintiff Fred Burrough**

a) On personal knowledge, Plaintiff Fred Burrough (hereinafter "Plaintiff" or "Burrough") is an individual who resides in Garland County, Arkansas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injury, a life-altering and debilitating condition. In or around April 2011, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary disease, a serious and potentially disabling lung condition. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In January 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Rajesh prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Rajesh was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Rajesh did not receive FDA warnings from Defendant.

e) Dr. Rajesh was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately December 2017, he began to experience many of the symptoms outlined in the FDA labeling, which include trouble breathing, coughing, difficulty with exertion, shortness of breath, weakness, pneumonia and fatigue. He was presented with a diagnosis of Amiodarone induced-pulmonary disease. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary disease, Plaintiff was a remarkably healthy and active individual. After developing these injuries, he was often fatigued and short of breath and required hospitalization. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary disease.

18. **Plaintiff Sonja Butler**

a) On personal knowledge, Plaintiff Sonja Butler, Personal Representative of the Estate of Raymond Butler, deceased, (hereinafter "Plaintiff" or "Butler") is an individual who resides in Ouachita County, Arkansas. Mr. Butler was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In February 2010, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a "rhythm medication," which turned out to be Amiodarone. As a proximate result of his Amiodarone use,

he developed Amiodarone-induced interstitial lung disease, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around February 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Kristopher Freeland prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Kristopher Freeland was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Freeland did not receive FDA warnings from Defendant.

e) Dr. Freeland was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately April 2017, he began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, chest pain, edema and respiratory failure. He was presented with a diagnosis of Amiodarone-induced interstitial lung disease and pulmonary toxicity. Intersitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Intersitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced interstitial lung disease, Mr. Butler was a healthy and active individual. After developing interstitial lung disease, he struggled to exert himself and was debilitated with weakness and shortness of breath. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced interstitial lung disease.

i) After developing Amiodarone-induced interstitial lung disease and respiratory failure, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring breathing assistance and oxygen. After spending several days in the hospital, Raymond Butler succumbed to his Amiodarone-induced interstitial lung disease and respiratory failure on June 20, 2017.

19. **Plaintiffs James Calvin and Helen Calvin**

a) On personal knowledge, Plaintiff James Calvin (hereinafter “Plaintiff” or “Calvin”) is an individual who resides in Asotin County, Washington. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed pulmonary fibrosis, which is a life-threatening and debilitating condition. In or around July 2014, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed pulmonary fibrosis and Amiodarone-induced lung toxicity, both serious and potentially deadly complications. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around July 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Dennis Mountjoy prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-

threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Dennis Mountjoy was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Mountjoy did not receive FDA warnings from Defendant.

e) Dr. Mountjoy was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately January 2015, he began to experience many of the symptoms outlined in the FDA labeling, which include burning in the sinuses and lung, coughing up blood, weakness and difficulty breathing. He underwent lung surgery in April 2015, and, at that time, he was diagnosed with pulmonary fibrosis. Pulmonary fibrosis is a debilitating, chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after his diagnosis that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing pulmonary fibrosis and Amiodarone-induced lung toxicity, he was a remarkably healthy and active individual. He spent a great deal of time with his wife and

daughter, enjoying family events and functions. Only a few months later, after developing pulmonary fibrosis, he could not walk across the room. He has developed cirrhosis of the liver as well due to the Amiodarone use and is totally homebound. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) Additionally, Plaintiff, Helen Calvin is the spouse of the Plaintiff James Calvin, and resides with her spouse, and she depended on James Calvin to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff James Calvin, Plaintiff Helen Calvin has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

20. **Plaintiffs Delbert Carter and Bobbie Carter**

a) On personal knowledge, Plaintiff Delbert Carter (hereinafter "Plaintiff" or "Carter") is an individual who resides in Craighead County, Arkansas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injury and vision loss, life-threatening and debilitating conditions. In or around September 2013, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary injury and vision loss, serious and potentially deadly diseases. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe

and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around September 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. W. Brian Bailey prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. W. Brian Bailey was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Bailey did not receive FDA warnings from Defendant.

e) Dr. Bailey was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately June 2015, he began to experience many of the symptoms outlined in the FDA labeling, which include vision loss, blurry vision, spots in his eyes,

and shortness of breath, wheezing, trouble breathing, coughing, chest pain, fatigue, weakness, tremors, nausea and difficulty with exertion. He was subsequently presented with a diagnosis of Amiodarone-induced vision loss and impairment as well as pulmonary injury. Amiodarone-induced pulmonary injury is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary injury is extremely poor. Amiodarone-induced pulmonary injury causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing pulmonary injury and vision loss, Plaintiff was a remarkably healthy and active individual. After developing pulmonary injury and vision loss and injury, he could not walk across the room. He now requires use of oxygen to breathe. His vision is constantly blurry, causing difficulty in reading and driving. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary injury and vision loss including congestive heart failure.

i) Additionally, Plaintiff Bobbie Carter is the spouse of the Plaintiff Delbert Carter, and resides with her spouse, and she depended on Delbert Carter to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Delbert Carter, Plaintiff Bobbie Carter has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

21. Plaintiff Karmen Caruso

a) On personal knowledge, Plaintiff Karmen Caruso (hereinafter "Plaintiff" or "Caruso") is an individual who resides in Lawrence County, Indiana. She was prescribed,

purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed pulmonary fibrosis, which is a life-threatening and debilitating condition. In or around June 2017, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed pulmonary fibrosis, a serious and potentially deadly complication. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around June 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Raza prescribed her a course of 200 mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as

prescribed. Dr. Raza was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Raza did not receive FDA warnings from Defendant.

e) Dr. Raza was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and her prescription was for an "off-label" use.

f) Beginning in approximately July 2018, she began to experience many of the symptoms outlined in the FDA labeling, which include trouble breathing, shortness of breath, coughing, weakness, edema, dizziness, chest pain and fatigue. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Amiodarone-induced pulmonary fibrosis is a debilitating, chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after her diagnosis that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing pulmonary fibrosis and Amiodarone-induced lung toxicity, she was a remarkably healthy and active individual. After developing pulmonary fibrosis, she is often fatigued and short of breath requiring hospitalization. She also suffers from a litany of other health

problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis.

22. **Plaintiffs Raniere Caserta and Couchita Caserta**

a) On personal knowledge, Plaintiff Raniere Caserta (hereinafter “Plaintiff” or “Caserta”) is an individual who resides in Miami-Dade County, Florida. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease, a life-threatening and debilitating condition. In or around August 2009, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary disease, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In August 2009, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with

the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Pablo Vivas prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Pablo Vivas was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Vivas did not receive FDA warnings from Defendant.

e) Dr. Vivas was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately February 2016, he began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing and fatigue. He was presented with a diagnosis of Amiodarone-induced pulmonary disease. Amiodarone-induced pulmonary disease is a debilitating, chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for the lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale

of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing lung toxicity, he was a remarkably healthy and active individual. After developing lung toxicity, he struggles to exert himself and to enjoy the things he once did. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary injury.

i) Additionally, Plaintiff, Couchita Caserta, is the spouse of the Plaintiff Raniere Caserta, and resides with her spouse, and she depended on Raniere Caserta to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Raniere Caserta, Plaintiff Couchita Caserta has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

23. **Plaintiff John Chapman, Sr.**

a) On personal knowledge, Plaintiff John Chapman, Sr. (hereinafter "Plaintiff" or "Chapman") is an individual who resides in Hamblen County, Tennessee. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injuries, and vision injury and loss, which can be life-threatening and debilitating conditions. In or around January 2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary injury, including COPD, pulmonary edema, and vision loss/injury, which can be serious and potentially deadly diseases. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In January 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Sunil T. Ramaprasad prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Sunil T. Ramaprasad was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Ramaprasad did not receive FDA warnings from Defendant.

e) Dr. Ramaprasad was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately February 2015, he began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, coughing, fatigue, vision loss, edema, abnormal kidney and thyroid function, weakness, anemia, anxiety and depression. After several hospitalizations, frequent pneumonias, and other complications, he was presented with a diagnosis of Amiodarone-induced pulmonary injuries, including COPD, pulmonary embolism and pulmonary edema. Amiodarone-induced pulmonary injuries are debilitating chronic, progressive conditions that only worsen over time. The survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly. In addition to pulmonary disease, he was also diagnosed with Amiodarone-induced vision loss, and thyroid and kidney injuries.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary injuries, vision loss, kidney and thyroid disease, Plaintiff was a remarkably healthy and active individual. After developing pulmonary injuries, vision loss, kidney and thyroid disease, he struggled to exert himself, his vision was significantly impaired requiring assistance for regular tasks, he required cataracts surgery, and became anemic among other complications. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary, vision, thyroid and kidney injuries.

24. **Plaintiff Lois Childs**

a) On personal knowledge, Plaintiff Lois Childs (hereinafter "Plaintiff" or "Childs") is an individual who resides in New Haven County, Connecticut. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause

thereof, developed Amiodarone-induced vision loss and acute pulmonary fibrosis, a life-threatening and debilitating lung condition. In 2007 she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted sold for “off-label” use by them.

d) In March 2009, as a result of the long term and pervasive promotional activities of brand innovator Wyeth and other Defendants to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Mark Marieb prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Mark Marieb was a victim of the long term and successful

promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Marieb did not receive FDA warnings from Defendant.

e) Dr. Marieb was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and her prescription was for an "off-label" use.

f) Beginning in approximately February 2012, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, vision loss, abnormal thyroid function, weakness, and difficulty with exertion. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary, Plaintiff was a remarkably healthy and active individual. After developing these injuries, she could not easily exert herself, was often fatigued and short of breath. She also and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis.

25. **Plaintiffs Noel Cleckler and Frances Cleckler**

a) On personal knowledge, Plaintiff Noel Cleckler (hereinafter “Plaintiff” or “Cleckler”) is an individual who resides in Taylor County, Texas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease and vision loss, a life-threatening and debilitating condition. In or around 2014, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary disease and vision injury, a serious and potentially disabling condition. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In approximately 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Patel

prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Patel was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Patel did not receive FDA warnings from Defendant.

e) Dr. Patel was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately 2015, he began to experience many of the symptoms outlined in the FDA labeling, which include vision loss, blurry vision, cataracts, and shortness of breath, wheezing, trouble breathing, coughing, fatigue, chest pain, weakness, and dizziness. He was presented with a diagnosis of Amiodarone-induced pulmonary disease and vision loss. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing vision injuries and pulmonary disease, Plaintiff was a remarkably healthy and active individual. After developing these complications, he struggles to exert himself and is often short of breath. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary disease and vision loss.

i) Additionally, Plaintiff Frances Cleckler is the spouse of the Plaintiff Noel Cleckler and resides with her spouse, and she depended on Noel Cleckler, to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Noel Cleckler, Plaintiff Frances Cleckler, has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

26. **Plaintiff Jo Ann Collings**

a) On personal knowledge, Plaintiff Jo Ann Collings, Personal Representative of the Estate of Roberts Collings, deceased, (hereinafter "Plaintiff" or "Collings") is an individual who resides in Calcasieu County, Louisiana. Mr. Collings was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease, a life-threatening and debilitating condition. In June 2017, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a "rhythm medication," which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced interstitial lung disease, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe

and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around June 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. James McKinnie prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. James McKinnie was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. McKinnie did not receive FDA warnings from Defendant.

e) Dr. McKinnie was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately July 2017, he began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble

breathing, coughing, fatigue and weakness. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity as well as interstitial pneumonia and pulmonary edema. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary toxicity and interstitial lung disease is extremely poor. Pulmonary toxicity and interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary injuries, disease, Mr. Collings was a healthy and active individual. After developing pulmonary toxicity and interstitial lung disease, he could not exert himself or adequately breathe on his own. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity and interstitial lung disease.

i) After developing Amiodarone-induced pulmonary toxicity and interstitial lung disease, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring breathing assistance, oxygen, and life support. After spending nearly two weeks in the hospital, Robert Collings succumbed to his Amiodarone-induced pulmonary toxicity and respiratory failure on July 23, 2017.

27. **Plaintiffs Kenneth Collins and Kim Collins**

a) On personal knowledge, Plaintiff Kenneth Collins (hereinafter "Plaintiff" or "Collins") is an individual who resides in Knox County, Tennessee. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injury and vision loss, life-threatening and debilitating conditions. In or around April 2013, he was diagnosed as suffering from atrial

fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary disease, a serious and potentially deadly lung disease, as well as vision loss. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In January 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Kyle McCoy prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Kyle McCoy was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to

Plaintiff and Plaintiff's decision to take it. Also, again, Dr. McCoy did not receive FDA warnings from Defendant.

e) Dr. McCoy was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately June 2016, he began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, fatigue, chest pain, weakness, blurred vision and vision loss, skin rashes, dizziness and numbness. He was presented with a diagnosis of Amiodarone-induced pulmonary disease and vision loss. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary disease and vision loss, Plaintiff was a remarkably healthy and active individual. After developing pulmonary injury and vision loss, he struggles to exert himself and to enjoy the things he once did. He also lost weight and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary injury.

i) Additionally, Plaintiff Kim Collins is the spouse of the Plaintiff Kenneth Collins, and resides with her spouse, and she depended on Kenneth Collins to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to

Plaintiff Kenneth Collins, Plaintiff Kim Collins has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

28. **Plaintiff Rachel Cook**

a) On personal knowledge, Plaintiff Rachel Cook (hereinafter "Plaintiff" or "Cook") is an individual who resides in Scott County, Kentucky. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed pulmonary fibrosis, which is a life-threatening and debilitating condition. In or around October 2017, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed pulmonary fibrosis, a serious and potentially deadly complication. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for "off-label" use by them.

d) In or around October 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Joseph Thomas prescribed her a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Joseph Thomas was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Thomas did not receive FDA warnings from Defendant.

e) Dr. Thomas was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and her prescription was for an "off-label" use.

f) Beginning in approximately March 2018, she began to experience many of the symptoms outlined in the FDA labeling, which include trouble breathing, shortness of breath, coughing, vision loss, weakness, edema, dizziness, chest pain and fatigue. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Amiodarone-induced pulmonary fibrosis is a debilitating, chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after her diagnosis that she

became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis and Amiodarone-induced pulmonary fibrosis, she was a remarkably healthy and active individual. After developing pulmonary fibrosis, she is often fatigued and short of breath and requires assistance with daily life activities. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis.

29. **Plaintiffs Jennith Coontz and Donald Coontz**

a) On personal knowledge, Plaintiff Jennith Coontz (hereinafter "Plaintiff" or "Coontz") is an individual who resides in Lincoln County, Kentucky. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating lung condition. In June 2015 she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted sold for “off-label” use by them.

d) In June 2015, as a result of the long term and pervasive promotional activities of brand innovator Wyeth and other Defendants to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because she did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Angela Mahann prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Angela Mahann was a victim of the long term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Mahann did not receive FDA warnings from Defendant.

e) Dr. Mahann was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and her prescription was for an “off-label” use.

f) Beginning in approximately August, she began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, vision loss, headaches, fatigue and loss of hair. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for

individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary, Plaintiff was a remarkably healthy and active individual. After developing these injuries, she could not easily exert herself, was often fatigued and short of breath, and she also lost total vision in her right eye, required surgery on both eyes for Plateau Iris Syndrome, which is caused by Amiodarone use. She also and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis.

i) Additionally, Plaintiff, Donald Coontz, is the spouse of the Plaintiff Jennith Coontz, and resides with his spouse, and he depended on Jennith Coontz to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Jennith Coontz, Plaintiff Donald Coontz has in the past and will in the future suffer and incur loss of her consortium, loss of his spouse's services, the cost and expense of having medical care, attention and treatment for his spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for her.

30. **Plaintiff Mary Cox**

a) On personal knowledge, Plaintiff Mary Cox (hereinafter "Plaintiff" or "Cox") is an individual who resides in Sevier County, Tennessee. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and vision complications, life-altering and debilitating conditions. In or around October 2010, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was

subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed vision loss and other vision complications from Amiodarone toxicity. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In October 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Thomas Ayres prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Thomas Ayres was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to

Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Ayres did not receive FDA warnings from Defendant.

e) Dr. Ayres was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and her prescription was for an "off-label" use.

f) Beginning in approximately February 2016, she began to experience many of the symptoms outlined in the FDA labeling, which include vision loss, multiple vision complications including pseudophakia, deposits in her cornea, vitreous detachment and retinal complications, coughing, tiredness and weakness. Her vision is now blurry and has required surgery and several medical treatments, and has limited her ability to maintain her previous lifestyle.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing vision loss and impairment, she was a remarkably healthy and active individual. She enjoyed vigorous exercise and was an avid reader. After developing vision impairment, she struggled to enjoy her normal activities and required eye surgery for her complications related to her Amiodarone use.

31. **Plaintiff Mary Davis**

a) On personal knowledge, Plaintiff Mary Davis (hereinafter "Plaintiff" or "Davis") is an individual who resides in Waukesha County, Wisconsin. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-altering and debilitating condition. In or around January 2012, she was diagnosed as suffering from atrial fibrillation ("A-

fib”), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In approximately January 2012, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. J. Wright prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. J. Wright was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe

Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Wright did not receive FDA warnings from Defendant.

e) Dr. Wright was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately January 2017, she began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, fatigue, chest pain, weakness, and vision loss. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis, she can no longer walk daily, and she struggles to exert herself, and requires use of oxygen. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis.

32. **Plaintiff Vernon DeBoard**

a) On personal knowledge, Vernon DeBoard, individually and as Personal Representative of the Estate of Katherine DeBoard, deceased (hereinafter "Plaintiff" or

“DeBoard”) is an individual who resides in Butler County, Ohio. Mrs. DeBoard was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced liver toxicity, renal failure and pancreatitis, all life-threatening and debilitating conditions. In June 2013, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced liver toxicity, renal failure and pancreatitis, all serious and potentially deadly lung diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around June 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. M. Atia Khalid prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-

threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. M. Atia Khalid was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Khalid did not receive FDA warnings from Defendant.

e) Dr. Khalid was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately January 2015, she began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, abdominal pain, weakness, difficulty with exertion, abnormal kidney function, liver toxicity, and abnormal pancreas function. She was presented with a diagnosis of Amiodarone-induced liver toxicity, acute renal failure and acute pancreatitis. These life-threatening injuries are debilitating chronic, progressive conditions that only worsen over time. The five-year survival rate for individuals with organ toxicity is extremely poor.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing liver toxicity, renal failure and pancreatitis, Plaintiff was a healthy and active individual. After developing these multi-organ injuries, she could not walk across the room and was frequently hospitalized. She also suffered from a litany of other health

problems related to her use of Amiodarone and medications used to treat his Amiodarone-induced injuries.

i) At some point in 2016, Mr. DeBoard discovered a Facebook page discussing the serious complications of Amiodarone, including pulmonary toxicity, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, he sought legal representation regarding his wife's injuries. The Facebook page in question was not published until 2015. It was not until he learned of these facts that he knew, or reasonably should have known, that the injuries his wife suffered were caused by wrongdoing on the part of the Defendants.

j) After developing Amiodarone-induced liver toxicity, renal failure, and pancreatitis, her condition deteriorated rapidly, requiring hospitalization. Her condition worsened, requiring a significant amount of time in the hospital. Katherine DeBoard succumbed to her Amiodarone-induced liver toxicity, renal failure and pancreatitis on February 11, 2015.

33. **Plaintiff Susan Fedorsha**

a) On personal knowledge, Plaintiff Susan Fedorsha, Personal Representative of the Estate of Joseph Fedorsha, deceased, (hereinafter "Plaintiff" or "Fedorsha") is an individual who resides in Maricopa County, Arizona. Mr. Fedorsha was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary fibrosis, a life-threatening and debilitating condition. In or around 2009, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a "rhythm medication," which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced acute pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe

and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around January 2012, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Drory Tendler prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Drory Tendler was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Tendler did not receive FDA warnings from Defendant.

e) Dr. Tendler was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately August 2015, he began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, difficulty

breathing, coughing and weakness. He was presented with a diagnosis of Amiodarone-induced acute pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Mr. Fedorsha was a healthy and active individual. After developing pulmonary fibrosis and respiratory failure, he could not exert himself and suffered from complicated pneumonias. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) After developing pulmonary fibrosis, his condition deteriorated rapidly. He could not adequately breathe on his own, requiring hospitalization, medical intervention and intensive care. After spending time in the intensive care unit in the hospital, Joseph Fedorsha succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on August 16, 2015.

34. **Plaintiffs Charles Fendley and Patricia Fendley**

a) On personal knowledge, Plaintiff Charles Fendley (hereinafter "Plaintiff" or "Fendley") is an individual who resides in Madison County, Mississippi. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss, a life-altering and debilitating condition. In or around October 2016, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be

Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced vision loss and injury, which is serious and potentially disabling. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In or around October 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Lawrence Sutton prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Lawrence Sutton was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Sutton did not receive FDA warnings from Defendant.

e) Dr. Sutton was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately June 2017, he began to experience many of the symptoms outlined in the FDA labeling, which include decreased visual acuity, blurry vision, dizziness, fatigue, poor coordination, weakness, and sudden vision loss to his left eye. He was presented with a diagnosis of Amiodarone-induced vision loss and cataract. Amiodarone-induced vision loss is a debilitating, chronic, progressive condition that is likely to worsen over time. Often the optic damage significantly impairs quality of life and cannot be reversed.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced vision loss, plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced vision loss, he struggles to independently perform the tasks of daily life and struggles to read, drive and enjoy television. He also suffers from a litany of other health problems related to his use of Amiodarone.

i) Additionally, Plaintiff, Patricia Fendley, is the spouse of the Plaintiff Charles Fendley, and resides with her spouse, and she depended on Charles Fendley to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Charles Fendley, Plaintiff Patricia Fendley has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

35. **Plaintiff Andrew Fancher**

a) On personal knowledge, Plaintiff Andrew Fancher, Personal Representative of the Estate of Julianne Wintker, deceased, (hereinafter “Plaintiff” or “Wintker”) is an individual who resides in Shelby County, Tennessee. Ms. Wintker was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced interstitial lung disease, a life-threatening and debilitating condition. In July 2017, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. Her cardiologist prescribed her a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced interstitial lung disease, a serious and potentially deadly lung disease. She received no warning from her physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around July 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA

warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Stewart Gardner prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Stewart Gardner was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Gardner did not receive FDA warnings from Defendant.

e) Dr. Gardner was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately September 2017, she began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue and weakness. She was presented with a diagnosis of Amiodarone-induced interstitial lung disease. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced interstitial lung disease, Ms. Wintker was a healthy and active individual. After developing interstitial lung disease, she struggled to exert himself and was debilitated with weakness and shortness of breath. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced interstitial lung disease.

i) After developing Amiodarone-induced interstitial lung disease, her condition deteriorated rapidly, requiring hospitalization. She could not adequately breathe on her own, requiring breathing assistance and oxygen use. After spending several days in the hospital, Julianne Wintker succumbed to her Amiodarone-induced interstitial lung disease and respiratory failure on November 17, 2017.

36. **Plaintiffs Diane Zarembo and Micah Gartman**

a) On personal knowledge, Plaintiff Diane Zarmebo (hereinafter “Plaintiff” or “Zarembo”) is an individual who resides in Houston County, Texas. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around August 2015, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced interstitial lung disease, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her

doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In August 2015 as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Humair Mirza prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Humair Mirza was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Mirza did not receive FDA warnings from Defendant.

e) Dr. Mirza was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately June 2015, she began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, chest pain, edema, and irregular heart rate. She was

presented with a diagnosis of Amiodarone-induced pulmonary disease. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing interstitial lung disease, she was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary disease, she struggles to exert herself and is often fatigued. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary injury.

i) Additionally, Plaintiff Micah Gartman is the spouse of the Plaintiff Diane Zaremba and resides with his spouse, and he depended on Diane Zarmebo to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Diane Zaremba, Plaintiff Micah Gartman, has in the past and will in the future suffer and incur loss of her consortium, loss of his spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

37. **Plaintiff Pamela Gibson**

a) On personal knowledge, Plaintiff Pamela Gibson (hereinafter "Plaintiff" or "Gibson") is an individual who resides in Franklin County, Ohio. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss/injury, a life-altering and debilitating condition. In or around October 2016, she was diagnosed as suffering from atrial fibrillation, which

is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced vision loss and injury, a serious and potentially disabling condition. She received no warning from her physician about these potential debilitating complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendant. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In or around October 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Juan Crestanello and Dr. Michael Murnane prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Juan Crestanello and Dr. Michael Murnane were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial

fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Crestanello and Dr. Murnane did not receive FDA warnings from Defendant.

e) Dr. Crestanello and Dr. Murnane were not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately October 2016, she began to experience many of the symptoms outlined in the FDA labeling, which include legal blindness, vision disturbances, optic nerve damage, floaters, trouble with coordination due to vision loss, trouble breathing, coughing, fatigue and weakness. She was presented with a diagnosis of Amiodarone-induced blindness and vision injury, including ischemic optic neuropathy in both eyes. Amiodarone-induced vision injury is debilitating and is known to worsen over time and may result in other visual complications including but not limited to, eye pain, irritation, floaters, retinal detachment, corneal disease, optic neuropathy, loss of visual acuity and peripheral vision, deposits within the eye, and cataracts. Amiodarone-induced vision loss/injury often cannot be corrected and causes a significant impairment on quality of life.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing vision injury, Plaintiff was a remarkably healthy and active individual. After developing vision loss and blindness, she could not live on her own and required full-time care to perform regular daily life activities. She also suffers from a litany of other health problems related to her use of Amiodarone.

38. **Plaintiff Ruth Glascoe**

a) On personal knowledge, Plaintiff Ruth Glascoe, Personal Representative of the Estate of William Glascoe, deceased, (hereinafter “Plaintiff” or “Glascoe”) is an individual who resides in Preble County, Ohio. Mr. Glascoe was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In January 2016, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around January 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA

warnings as a result of the Defendant's failure to adequately communicate such warnings, Dr. Allen Joseph Reid prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Allen Joseph Reid was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Reid did not receive FDA warnings from Defendant.

e) Dr. Reid was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately April 2016, he began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, difficulty sleeping, and oxygen dependence. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Mr. Glascoe was a healthy and active individual. After developing pulmonary fibrosis, he depended on oxygen around the clock. He required assistance for self-care needs and struggled with exertion. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) After developing pulmonary fibrosis, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring breathing assistance and oxygen use. William Glascoe succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on October 9, 2017.

39. **Plaintiff Barbara Grantham**

a) On personal knowledge, Plaintiff Barbara Grantham, Personal Representative of the Estate of Larry Grantham, deceased, (hereinafter “Plaintiff” or “Grantham”) is an individual who resides in Ford County, Kansas. Larry Grantham was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis and vision loss, a life-threatening and debilitating condition. In February 2015, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians

of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around March 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Muhammed Khan prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Muhammed Khan was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Khan did not receive FDA warnings from Defendant.

e) Dr. Khan was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately July 2015, he began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, difficulty breathing, coughing, fatigue, weakness, vision loss, vision floaters, and weight loss. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a

debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Mr. Grantham was a healthy and active individual. After developing pulmonary fibrosis, he was constantly fatigued and could barely exert himself, and he also required oxygen to breathe. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) After developing pulmonary fibrosis and vision loss, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring a BiPaP machine and admittance to the intensive care unit for medical intervention and care. His lungs continued to weaken resulting in acute respiratory failure. After spending the majority of a month in the intensive care unit in the hospital, Larry Grantham succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on August 9, 2015.

40. **Plaintiffs Francis Gromadzki and Lee Ann Gromadzki**

a) Plaintiff, Francis Gromadzki (hereinafter "Plaintiff" or "Gromadzki") is an individual who resides in Carteret County, North Carolina. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In December 2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his

Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In December 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Marwan Mihyu prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Marwan Mihyu was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Mihyu did not receive FDA warnings from Defendant.

e) Dr. Mihyu was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately April 2016, he began to experience many of the symptoms outlined in the FDA labeling, which include loss of vision, shaking in his hands, exertion, shortness of breath, anemia, coughing, tiredness, weakness, difficulty sleeping and weight loss. He was presented with a diagnosis of pulmonary fibrosis, hypothyroidism and loss of vision. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, he was a remarkably healthy and active individual. After developing pulmonary fibrosis, he became extremely weak and required multiple blood transfusions. He has significant loss of vision and he experiences constant pain in his ribs and back. His skin turned yellow and he suffers from a litany of other health problems apparently related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis. He developed hypothyroidism and chronic kidney and liver disease.

i) Additionally, Plaintiff, Lee Ann Gromadzki is the spouse of the Plaintiff Francis Gromadzki, and resides with her spouse, and she depended on Plaintiff, Francis Gromadzki to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff, Francis Gromadzki, Plaintiff, Lee Ann Gromadzki has in the past

and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

41. **Plaintiff Carolyn Hale**

a) On personal knowledge, Plaintiff Carolyn Hale, Personal Representative of the Estate of Benny Hale, deceased, (hereinafter "Plaintiff" or "Hale") is an individual who resides in Madison County, Alabama. Mr. Hale was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary toxicity and respiratory failure, a life-threatening and debilitating condition. In or around January 2018, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a "rhythm medication," which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced acute pulmonary toxicity and respiratory failure, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed

Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around January 2018, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. John Hartley prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. John Hartley was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Hartley did not receive FDA warnings from Defendant.

e) Dr. Hartley was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately March 2018, he began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, chest pain, edema and respiratory failure. He was presented with a diagnosis of Amiodarone-induced respiratory failure and pulmonary toxicity. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary toxicity is extremely poor. Pulmonary toxicity and respiratory failure causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary toxicity and respiratory failure, Mr. Hale was a healthy and active individual. After developing Amiodarone-induced pulmonary toxicity and respiratory failure, he struggled to exert himself and was debilitated with weakness and shortness of breath. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity and respiratory failure.

i) After developing Amiodarone-induced pulmonary toxicity and respiratory failure, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring oxygen use and a ventilator. After spending several days in the hospital, Benny Hale succumbed to his Amiodarone-induced pulmonary toxicity and respiratory failure on April 12, 2018.

42. **Plaintiffs Eugene Hamilton and Joann Hamilton**

a) On personal knowledge, Plaintiff Eugene Hamilton (hereinafter "Plaintiff" or "Hamilton") is an individual who resides in St. Joseph County, Michigan. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and vision deterioration, a life-altering and debilitating condition. In or around 2006, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced optic neuropathy resulting in ischemic optic neuropathy causing vision loss and blindness. He received no warning from his physician about these potential life-threatening complications, nor

did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In 2006, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Xiaoke Liv prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Xiaoke Liv was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Liv did not receive FDA warnings from Defendant.

e) Dr. Liv was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its

bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately September 2016, he began to experience many of the symptoms outlined in the FDA labeling, which include impaired vision, spots before his eyes, dizziness, faintness and headaches. The loss of vision came on quickly. He woke up on September 19, 2016 with no peripheral vision. It was determined that the vision loss was caused by his taking Amiodarone. The Amiodarone treatment was stopped.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced vision loss, plaintiff was a remarkably healthy and active individual. He now cannot enjoy reading, watching television and everyday activities. He also suffers from a litany of other health problems related to his use of Amiodarone.

i) Additionally, Plaintiff, Joann Hamilton, is the spouse of the Plaintiff Eugene Hamilton, and resides with her spouse, and she depended on Eugene Hamilton to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Eugene Hamilton, Plaintiff Joann Hamilton has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse’s services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

43. **Plaintiff Shirley Hart**

a) Plaintiff Shirley Hart (hereinafter “Plaintiff” or Hart”) is an individual who resides in Bowie County, Texas. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Zydus and potentially other manufacturers and as a proximate cause thereof, developed Amiodarone induced lung toxicity, a life-threatening and debilitating condition. In or

around January 2010, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed pulmonary complications. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around January 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Blake Norris prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Blake Norris was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related

to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Norris did not receive FDA warnings from Defendant.

e) Dr. Norris was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiffs was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in or around May 2010, she began to experience many of the symptoms outlined in the FDA labeling, which include difficulty breathing and shortness of breath, exhaustion, dizziness, weight loss, irregular heart rate, chest pains, swelling of the extremities, as well as stress and depression. After several hospital admissions and treatment for multiple pneumonias, she had suffered Pulmonary Complications such as shortness of breath, lung scarring, sleep apnea, fatigue, and has required breathing assistance. Her pulmonary complications are debilitating and have drastically affected her quality of life.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary complications, she was a healthy and active individual. After developing pulmonary complications, she has been unable to work or enjoy the day-to-day activities of life. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her pulmonary complications such as vision loss, hypothyroid disease, congestive heart failure, depression, sleep apnea, and irregular bleeding.

44. **Plaintiff Deborah Hensley**

a) On personal knowledge, Plaintiff Deborah Hensley (hereinafter "Plaintiff" or "Hensley") is an individual who resides in Snohomish County, Washington. She was prescribed,

purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed pulmonary disease, which is a life-threatening and debilitating condition. In or around July 2016, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed pulmonary disease, a serious and potentially deadly complication. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around July 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. David Nelson prescribed her a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug

Amiodarone as prescribed. Dr. David Nelson was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Nelson did not receive FDA warnings from Defendant.

e) Dr. Nelson was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and her prescription was for an "off-label" use.

f) Beginning in approximately July 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, nervousness, nausea, and abdominal pain. She was presented with a diagnosis of Amiodarone-induced pulmonary disease. Amiodarone-induced pulmonary disease is a debilitating, chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after her diagnosis that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing Amiodarone-induced pulmonary disease, she was a remarkably healthy and active individual. After developing pulmonary disease, she was often hospitalized for difficulty breathing, she struggled to walk independently, and requires full-time use of oxygen.

She also lost weight and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary disease.

45. **Plaintiff Henry Henson**

a) On personal knowledge, Plaintiff Henry Henson, Personal Representative of the Estate of Jane Henson, deceased, (hereinafter “Plaintiff” or “Henson”) is an individual who resides in Norfolk County, Virginia. Mrs. Henson was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute interstitial lung disease, a life-threatening and debilitating condition. In November 2015, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. Her cardiologist prescribed her a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced acute interstitial lung disease, a serious and potentially deadly lung disease. She received no warning from her physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around November 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Thomas Klevan prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Thomas Klevan was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Klevan did not receive FDA warnings from Defendant.

e) Dr. Klevan was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately May 2016, she began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, difficulty breathing, coughing, fatigue, weakness, and vision loss. She was presented with a diagnosis of Amiodarone-induced acute interstitial lung disease. Amiodarone-induced acute intersitil lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Amiodarone-induced intersitil lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she

became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced interstitial lung disease, Mrs. Henson was a healthy and active individual. After developing interstitial lung disease, she could not exert herself and suffered from severe pneumonias. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced acute interstitial lung disease.

i) After developing Amiodarone-induced acute interstitial lung disease, her condition deteriorated rapidly, requiring extended hospitalization. She could not adequately breathe on her own, requiring breathing assistance and oxygen use. After spending almost a month in the hospital, Jane Henson succumbed to her Amiodarone-induced interstitial lung disease and respiratory failure on June 27, 2016.

46. **Plaintiff Rex Hess**

a) On personal knowledge, Plaintiff Rex Hess (hereinafter "Plaintiff" or "Hess") is an individual who resides in Salt Lake County, Utah. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed vision loss from Amiodarone toxicity, a life-altering and debilitating condition. In or around May 2013, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed vision loss from Amiodarone. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe

and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In September 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Michael Eifling prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Michael Eifling was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Eifling did not receive FDA warnings from Defendant.

e) Dr. Eifling was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately April 2016, he began to experience many of the symptoms outlined in the FDA labeling, which include blurred vision and loss of vision, eye

irritation, weakness, shortness of breath, fatigue and dizziness. He was presented with a diagnosis of Amiodarone-induced vision injury and loss. Amiodarone-induced vision loss is a debilitating condition that worsens over time, resulting in other visual complications. Amiodarone-induced vision loss/injury often cannot be corrected and causes a significant impairment on quality of life.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone toxicity, he was a remarkably healthy and active individual. After developing Amiodarone-induced vision loss, he struggles to enjoy reading, driving and watching television. He is not able to exert himself and to enjoy the things he once did. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced vision loss/injury.

47. **Plaintiff Delbert Hinkle**

a) On personal knowledge, Plaintiff, Delbert Hinkle (hereinafter "Plaintiff" or "Hinkle") is an individual who resides in Nicholas County, West Virginia. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis and COPD, a life-threatening and debilitating condition. In or around 2010, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In or around 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to communicate such warnings, Dr. Haven Wall prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Haven Wall was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Wall did not receive FDA warnings from Defendant.

e) Dr. Wall was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately August 2012, he began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, coughing, fatigue, weakness, vision loss and cataracts, muscle spasms, thyroid disease and difficulty walking. He was subsequently presented with a diagnosis of Amiodarone-induced pulmonary fibrosis and COPS. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary fibrosis and COPD, plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis and COPD, he could not walk across the room. He suffered several pneumonias, requiring medical treatment frequently. He required the use of oxygen to assist with his severe airway restriction. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

48. **Plaintiff Sara Huff**

a) On personal knowledge, Plaintiff Sara Huff, Personal Representative of the Estate of Mildred Cagle, deceased, (hereinafter "Plaintiff" or "Cagle") is an individual who resides in Pulaski County, Arkansas. Ms. Cagle was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around 2012, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. Her cardiologist prescribed her a "rhythm

medication,” which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around 2012, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Douglas Holloway prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Douglas Holloway was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to

prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Holloway did not receive FDA warnings from Defendant.

e) Dr. Holloway was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately December 2012, she began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, difficulty breathing, coughing, fatigue, edema, nausea and weakness. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis disease is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary fibrosis, Ms. Cagle was a healthy and active individual. After developing interstitial lung disease, she could not exert herself and frequently suffered from pneumonia. She also required regular use of oxygen and suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis.

i) After developing Amiodarone-induced pulmonary fibrosis, her condition deteriorated rapidly. She could not breathe adequately and developed pleural effusion requiring

medical treatment and care. After spending significant time in the hospital, Mildred Cagle succumbed to her Amiodarone-induced pulmonary fibrosis on December 16, 2014.

49. **Plaintiffs Clinton Humphrey and Tenna Humphrey**

a) On personal knowledge, Plaintiff Clinton Humphrey hereinafter “Plaintiff” or “Humphrey”) is an individual who resides in Santa Rosa County, Florida. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced thyroid injury a life-threatening and debilitating condition. In or around January 2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced hyperthyroidism disease, a serious and potentially deadly lung disease, as well as vision loss. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around March 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below,

along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Vardenra Panchamukhi, prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Vardenra Panchamukhi was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Panchamukhi did not receive FDA warnings from Defendant.

e) Dr. Panchamukhi was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately March 2015, he began to experience many of the symptoms outlined in the FDA labeling, which include confusion, tremors, memory loss, fatigue, weakness, and poor coordination. He was presented with a diagnosis of amiodarone induced hyperthyroidism. Amiodarone induced hyperthyroidism is a debilitating chronic, progressive condition that may worsen over time resulting in further complications.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing hyperthyroidism, he was a remarkably healthy and active individual. After developing amiodarone induced thyroid disease, he was often weak, confused

and struggled to exert himself. He also suffers from a litany of other health problems related to his use of amiodarone and medications used to treat his amiodarone induced thyroid disease.

i) Additionally, Plaintiff, Tenna Humphrey, is the spouse of the Plaintiff Clinton Humphrey, and resides with her spouse, and she depended on Clinton Humphrey to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Clinton Humphrey, Plaintiff Tenna Humphrey has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

50. **Plaintiff Braha Jackson**

a) On personal knowledge, Plaintiff Braha Jackson (hereinafter "Plaintiff" or "Jackson") is an individual who resides in Anderson County, Tennessee. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease, a life-altering and debilitating condition. In or around February 2011, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, she developed Amiodarone-induced pulmonary disease, a serious and potentially deadly lung injury. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians

of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In approximately February 2011, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Sharma prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Sharma was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Sharma did not receive FDA warnings from Defendant.

e) Dr. Sharma was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately November 2016, she began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, chest pain, weakness, dizziness and edema. She was presented with a diagnosis of Amiodarone-induced pulmonary disease and pulmonary edema. Amiodarone-

induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary disease and pulmonary edema, Plaintiff was a remarkably healthy and active individual. After developing pulmonary disease and pulmonary edema, she struggles to exert herself and is often short of breath. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary injuries.

51. **Plaintiff Doris Johnson**

a) On personal knowledge, Plaintiff Doris Johnson (hereinafter "Plaintiff" or "Johnson") is an individual who resides in Knox County, Tennessee. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and pulmonary fibrosis, both life-altering and debilitating conditions. In or around September 2014, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis and vision loss, serious and potentially disabling conditions. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around September 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Brian Adams prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Brian Adams was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Adams did not receive FDA warnings from Defendant.

e) Dr. Adams was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its

bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately July 2015, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include vision loss, deposits in eye, floaters, poor coordination due to vision loss, tremors, trouble breathing, shortness of breath, coughing, weakness, edema, chest pain, and fatigue. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis and vision loss. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary fibrosis and vision loss Plaintiff was a remarkably healthy and active individual. After developing these injuries, she could not easily read or drive and she is often fatigued and short of breath, requiring assistance with daily life activities. She also and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced vision injury and pulmonary fibrosis.

52. **Plaintiff Michael Johnston**

a) On personal knowledge, Plaintiff Michael Johnston, Personal Representative of the Estate of Patricia Johnson, deceased, (hereinafter “Plaintiff” or “Johnson”) is an individual who resides in Lake County, Indiana. Ms. Johnson was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed

Amiodarone-induced acute pulmonary fibrosis, a life-threatening and debilitating condition. In or around February 2015, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. Her cardiologist prescribed her a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced acute pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around February 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because they did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Yvette Lozano and Dr. Marzenna Schoeneich prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Yvette Lozano and Dr. Marzenna Schoeneich were victims of the long-term and successful promotional efforts of brand

innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Lozano and Dr. Schoeneich did not receive FDA warnings from Defendant.

e) Dr. Lozano and Dr. Schoeneich were not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately November 2015, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, dizziness and abnormal kidney function. She was presented with a diagnosis of Amiodarone-induced acute pulmonary fibrosis. Amiodarone-induced acute pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced acute pulmonary fibrosis disease is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced acute pulmonary fibrosis, Ms. Johnson was a healthy and active individual. After developing Amiodarone-induced pulmonary fibrosis, she became increasingly weak and struggled to breathe on her own. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced acute pulmonary fibrosis.

i) After developing Amiodarone-induced acute pulmonary fibrosis, her condition deteriorated rapidly, requiring hospitalization. She quickly required full-time use of oxygen, intubation and eventually ventilation. After battling several pneumonias, and being in and out of the hospital, she suffered respiratory arrest. Patricia Johnson succumbed to her Amiodarone-induced acute pulmonary fibrosis on January 18, 2016.

53. **Plaintiffs Pink Jones and Annie Jones**

a) On personal knowledge, Plaintiff Pink Jones (hereinafter “Plaintiff” or “Jones”) is an individual who resides in Bradley County, Tennessee. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully here, which was manufactured, promoted, supplied and/or distributed by Zydus and potentially other manufacturers. In or around January 2011 he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed interstitial lung disease, pulmonary toxicity and vision damage, potentially life-threatening diseases. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendant. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In or around January 2011, as a result of the long term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Brian Mitchell prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Mitchell was a victim of Wyeth’s long term and successful promotional efforts as well as Zydus and potentially other manufacturers’ sales efforts that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Mitchell did not receive FDA warnings from Defendant.

e) Dr. Mitchell was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately August 2017, he began to experience many of the symptoms outlined in the FDA labeling, which include trouble breathing, shortness of breath,

coughing, weakness, vision loss, dizziness, chest pain, headaches and fatigue. He was presented with a diagnosis of interstitial lung disease and pulmonary toxicity and corneal deposits causing vision damage. Interstitial lung disease is a debilitating chronic, progressive lung condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Interstitial lung disease pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, only later did he become aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing interstitial lung disease and pulmonary toxicity and vision damage, Plaintiff was a healthy and very active individual. After developing these complications, he is often weak and short of breath. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his pulmonary disease.

i) Additionally, Plaintiff Annie Jones is the spouse of the Plaintiff Pink Jones, and resides with her spouse, and she depended on Pink Jones to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Pink Jones, Plaintiff Annie Jones has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

54. **Plaintiff Stephanie Kibodeaux**

a) On personal knowledge, Plaintiff Stephanie Kibodeaux, Personal Representative of the Estate of Latuis Kibodeaux, deceased, (hereinafter "Plaintiff" or "Kibodeaux") is an individual

who resides in Jefferson Davis Parish, Louisiana. Mr. Kibodeaux was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In December 2015, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a "rhythm medication," which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for "off-label" use by them.

d) In or around December 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. William Bailey prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and

ingested the drug Amiodarone as prescribed. Dr. William Bailey was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Bailey did not receive FDA warnings from Defendant.

e) Dr. Bailey was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately December 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness and chest pain. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Mr. Kibodeaux was a healthy and active individual. After developing pulmonary fibrosis, he struggled to exert himself, was very weak and went into respiratory failure. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) After developing pulmonary fibrosis, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring breathing assistance and oxygen use. After spending several days in the hospital, Latuis Kibodeaux succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on January 7, 2017.

55. Plaintiffs Barbara King and Samuel King

a) On personal knowledge, Plaintiff Barbara King (hereinafter “Plaintiff” or “King”) is an individual who resides in Richland County, South Carolina. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around September 2013, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around September 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Hendricks prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Hendricks was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Hendricks did not receive FDA warnings from Defendant.

e) Dr. Hendricks was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately June 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, tiredness, vision deterioration, weakness, nervousness, edema, oxygen dependence, and abnormal thyroid function. She was presented with a diagnosis of pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she

became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, she was a remarkably healthy and active individual. After developing pulmonary fibrosis, she could not walk across the room, and now requires constant dependence on oxygen. She also lost weight and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis, including an abnormal thyroid and vision problems.

i) Additionally, Plaintiff, Samuel King, is the spouse of the Plaintiff Barbara King, and resides with his spouse, and he depended on Barbara King to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Barbara King, Plaintiff Samuel King has in the past and will in the future suffer and incur loss of her consortium, loss of his spouse's services, the cost and expense of having medical care, attention and treatment for her, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

56. **Plaintiffs Dennis Koch and Barbara Koch**

a) On personal information, Plaintiff, Dennis Koch (hereinafter "Plaintiff" or "Koch") is an individual who resides in Wood County, Wisconsin. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, and vision loss, both life-threatening and debilitating conditions. In or around May 2016, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary toxicity, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In or around May 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because they did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Michael Bauman and Dr. Shereif Rezkalla prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Michael Bauman and Dr. Shereif Rezkalla were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Bauman and Dr. Rezkalla did not receive FDA warnings from Defendant.

e) Dr. Bauman and Dr. Rezkalla were not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use

of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) In approximately August 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include vision loss, shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, nervousness, edema, depression and anxiety. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. The survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing Amiodarone-induced pulmonary toxicity, he was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary toxicity, he struggles to exert himself and keep up with daily life activities. His vision loss and impairment has reduced his ability to enjoy things he once loved, such as reading. He also suffers from a litany of other health problems apparently related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary disease.

i) Additionally, Plaintiff, Barbara Koch is the spouse of the Plaintiff Dennis Koch, and resides with her spouse, and she depended on Plaintiff, Dennis Koch to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff, Dennis Koch, Plaintiff, Barbara Koch has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse’s services, the cost and expense of having

medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

57. **Plaintiff Mark Laganelli**

a) On personal knowledge, Mark Laganelli, Personal Representative of the Estate of Lawrence Laganelli deceased (hereinafter “Plaintiff” or “Laganelli”) is an individual who resides in Worcester County, Massachusetts. Mr. Laganelli was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary fibrosis, a life-threatening and debilitating condition. In or around June 2000, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed

Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In June 2000, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Stephen Pezella prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Stephen Pezella was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Pezella did not receive FDA warnings from Defendant.

e) Dr. Pezella was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately April 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, vision loss, edema, and itching and chest pain. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis and respiratory failure.

Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis, he struggled to exert himself, was often weak and suffered frequent pneumonias. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis including vision loss.

i) After developing pulmonary fibrosis his condition deteriorated rapidly, and his lungs collapsed requiring intensive care hospitalization. He could not adequately breathe on his own, requiring breathing assistance and oxygen use due to his pneumonia and respiratory failure. After spending several days in the hospital, Lawrence Laganelli succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on August 10, 2016.

58. **Plaintiff Beverly Landrum**

a) On personal knowledge, Plaintiff Beverly Landrum, Personal Representative of the Estate of John Landrum, Jr., deceased, (hereinafter "Plaintiff" or "Landrum") is an individual who resides in Union County, North Carolina. Mr. Landrum was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause

thereof, developed Amiodarone-induced acute pulmonary injury, a life-threatening and debilitating condition. In or around June 2016, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced acute pulmonary injury, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around June 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. John Russell Bailey prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. John Russell Bailey was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of

Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Bailey did not receive FDA warnings from Defendant.

e) Dr. Bailey was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately July 2016, he began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness and vision loss. He was presented with a diagnosis of Amiodarone-induced acute pulmonary injury, acute liver damage, kidney failure, and vision deterioration. Amiodarone-induced pulmonary injury is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary injury is extremely poor. Amiodarone-induced pulmonary injury causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary injury, Mr. Landrum was a healthy and active individual. He enjoyed spending quality time with his family and was able to perform daily activities. After developing these complications, he could not catch his breath and suffered from complicated pneumonias. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary injury.

i) After developing Amiodarone-induced pulmonary injury, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring hospitalization and medical intervention. After spending more than a month in the hospital, John Landrum, Jr. succumbed to his Amiodarone-induced pulmonary injury, liver injury, and kidney failure on August 11, 2016.

59. **Plaintiffs Daniel Leong and Lauran Leong**

a) On personal knowledge, Plaintiff Daniel Leong (hereinafter “Plaintiff” or “Leong”) is an individual who resides in Collin County, Texas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease, a life-threatening and debilitating condition. In or around July 2010, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced interstitial lung disease and pulmonary hypertension, both serious and potentially deadly lung diseases. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed

Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In November 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because they did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Franklin and Dr. Alan Donsky prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Franklin and Dr. Alan Donsky were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Franklin and Dr. Donsky did not receive FDA warnings from Defendant.

e) Dr. Franklin and Dr. Donsky were not aware that his Plaintiff’s of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately January 2011, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, fatigue, chest pain, weakness, anemia, and pulmonary hypertension. He was presented with a diagnosis of Amiodarone-induced interstitial lung disease. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced interstitial lung disease is extremely poor. Amiodarone-induced interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing interstitial lung disease and pulmonary hypertension, Plaintiff was a remarkably healthy and active physician who enjoyed spending time with his family. After developing amiodarone induced pulmonary disease, he struggles to exert himself, has required oxygen, develops frequent pneumonias and infections, and is often weak and fatigued. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary disease including anemia and an enlarged heart.

i) Additionally, Plaintiff Lauran Leong is the spouse of the Plaintiff Daniel Leong, and resides with her spouse, and she depended on Daniel Leong to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Daniel Leong, Plaintiff Lauran Leong has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

60. **Plaintiffs Francis Lombardi and Angela Lombardi**

a) On personal knowledge, Plaintiff Francis Lombardi (hereinafter "Plaintiff" or "Lombardi") is an individual who resides in Lee County, Florida. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendant and as a proximate cause thereof, developed Amiodarone-induced interstitial lung disease, a life-threatening and debilitating condition. In or around July 2016, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced interstitial lung disease. He received no

warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) July 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Daniel Fuleihan prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Daniel Fuleihan was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Fuleihan did not receive FDA warnings from Defendant.

e) Dr. Fuleihan was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial

fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately May 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, fatigue, weakness and dizziness. He was presented with a diagnosis of Amiodarone-induced interstitial lung disease. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced interstitial lung disease is extremely poor. Amiodarone-induced interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced interstitial lung disease, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced interstitial lung disease, he struggles to exert himself and suffers from frequent pneumonia. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced interstitial lung disease.

i) Additionally, Plaintiff Angela Lombardi is the spouse of the Plaintiff Francis Lombardi, and resides with her spouse, and she depended on Francis Lombardi to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Francis Lombardi, Plaintiff Angela Lombardi has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse’s services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

61. **Plaintiff Nancy Lovvorn**

a) On personal knowledge, Plaintiff Nancy Lovvorn, Personal Representative of the Estate of Frank Lovvorn, deceased, (hereinafter “Plaintiff” or “Lovvorn”) is an individual who resides in Autauga County, Alabama. Mr. Lovvorn was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary fibrosis, a life-threatening and debilitating condition. In December 2013, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced acute pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around January 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Williams

prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Williams was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Williams did not receive FDA warnings from Defendant.

e) Dr. Williams was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately 2014, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, edema, palpitations, and chest pain. He was presented with a diagnosis of Amiodarone-induced acute pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Mr. Lovvorn was a healthy and active individual. After developing Amiodarone-induced acute pulmonary fibrosis, he struggled to exert

himself, required oxygen and suffered frequent pneumonias. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced acute pulmonary fibrosis

i) After developing Amiodarone-induced acute pulmonary fibrosis, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, developed pneumonia, and required oxygen use. Frank Lovvorn succumbed to his Amiodarone-induced acute pulmonary fibrosis and respiratory failure on May 10, 2017.

62. **Plaintiff Kim Lee Lowe**

a) On personal knowledge, Plaintiff Kim Lee Lowe, Personal Representative of the Estate of JoAnn Lowe, deceased, (hereinafter “Plaintiff” or “Lowe”) is an individual who resides in Carroll County, Tennessee. Mrs. Lowe was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary toxicity, a life-threatening and debilitating condition. In August 2017, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. Her cardiologist prescribed her a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced acute pulmonary toxicity, a serious and potentially deadly lung disease. She received no warning from her physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around September 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. David Gibson prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. David Gibson was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Gibson did not receive FDA warnings from Defendant.

e) Dr. Gibson was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately October 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, and abdominal pain. She was presented with a diagnosis of Amiodarone-induced acute pulmonary toxicity. Amiodarone-induced acute pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-

induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced acute pulmonary toxicity, Mrs. Lowe was a healthy and active individual. After developing Amiodarone-induced acute pulmonary toxicity, she could not exert herself or adequately breathe on her own. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced acute pulmonary toxicity.

i) After developing Amiodarone-induced acute pulmonary toxicity, her condition deteriorated rapidly, requiring intensive care hospitalization. She could no longer breathe on her own, requiring a ventilator. After spending three weeks in the hospital, JoAnn Lowe succumbed to her Amiodarone-induced pulmonary toxicity and respiratory failure on March 11, 2018.

63. **Plaintiff Bernice Manzo**

a) On personal knowledge, Plaintiff Bernice Manzo (hereinafter "Plaintiff" or "Manzo") is an individual who resides in Denver County, Colorado. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease, a severe and debilitating vision condition. In approximately November 2016, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be amiodarone. As a proximate result of her amiodarone use, she developed amiodarone-induced pulmonary injury and vision loss, both serious and debilitating diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that

Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around November 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Michael Ptsasnik prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Michael Ptsasnik was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Ptsasnik did not receive FDA warnings from Defendant.

e) Dr. Ptsasnik was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to

her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately February 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include trouble breathing, shortness of coughing, difficulty with exertion, weakness, edema, dizziness, chest pain and fatigue. She was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary toxicity, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary disease, she is often short of breath requiring oxygen and has been hospitalized multiple times. She also suffers from a litany of other health problems related to her use of amiodarone and medications used to treat her amiodarone induced pulmonary and vision injuries.

64. **Plaintiff Robert Mason**

a) On personal knowledge, Plaintiff Robert Mason (hereinafter “Plaintiff” or “Mason”) is an individual who resides in Saginaw County, Michigan. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis and vision loss, life-threatening and debilitating conditions. In or around May 2005, he was diagnosed as suffering

from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis and vision damage, both serious and potentially disabling medical conditions. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In May 2005, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Badami prescribed Plaintiff a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Badami was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and

Plaintiff's decision to take it. Also, again, Dr. Badami did not receive FDA warnings from Defendant.

e) Dr. Badami was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately October 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, fatigue, coughing, blurry vision, vision loss, dizziness and weakness. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis and vision loss. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary fibrosis and vision loss, Plaintiff was a remarkably healthy and active individual. After developing these injuries, he could not easily exert himself and was often fatigued and weak. He also and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary injury.

65. **Plaintiff Glenda McGuffie**

a) On personal knowledge, Plaintiff Glenda McGuffie (hereinafter "Plaintiff" or "McGuffie") is an individual who resides in Jefferson County, Alabama. She was prescribed,

purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, which is a life-threatening and debilitating condition. In or around September 2015, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed pulmonary fibrosis, a serious and potentially deadly complication. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around September 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Raymond Workman prescribed her a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone

manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Raymond Workman was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Workman did not receive FDA warnings from Defendant.

e) Dr. Workman was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and her prescription was for an "off-label" use.

f) Beginning in approximately April 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, trouble breathing, coughing, wheezing, edema, kidney damage, weight changes, anxiety and fatigue. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Amiodarone-induced pulmonary fibrosis is a debilitating, chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after her diagnosis that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing pulmonary fibrosis and Amiodarone-induced pulmonary fibrosis, she was a remarkably healthy and active individual. After developing pulmonary fibrosis, she is often fatigued and short of breath, resulting in frequent pneumonias and hospitalizations.

She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis.

66. **Plaintiff Brenda Medler**

a) On personal knowledge, Plaintiff Brenda Medler, Personal Representative of the Estate of Robert Medler, deceased, (hereinafter “Plaintiff” or “Medler”) is an individual who resides in Shelby County, Tennessee. Mr. Medler was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, a life-threatening and debilitating condition. In May 2016, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary toxicity, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around May 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below,

along with the continuing sales efforts of Defendants, and because they did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Mark Crupie and Dr. Robert Pegram prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Mark Crupie and Dr. Robert Pegram were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Crupie and Dr. Pegram did not receive FDA warnings from Defendant.

e) Dr. Crupie and Dr. Pegram were not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately July 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, difficulty breathing, coughing, fatigue, weakness and chest pain. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale

of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary toxicity, Mr. Medler was a healthy and active individual. After developing Amiodarone-induced pulmonary toxicity, he could not exert himself. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity.

i) After developing Amiodarone-induced pulmonary toxicity, his condition deteriorated rapidly. His lungs continued to weaken and he could not breathe adequately, requiring intensive medical treatment and care. Robert Medler succumbed to his Amiodarone-induced pulmonary toxicity and respiratory failure on August 28, 2016.

67. **Plaintiff George Miller**

a) On personal knowledge, Plaintiff George Miller (hereinafter “Plaintiff” or “Miller”) is an individual who resides in Lapeer County, Michigan. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis and vision loss, both life-altering and debilitating conditions. In or around August 2008, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis and vision loss, serious and potentially disabling conditions. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor

receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around August 2008, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Patel prescribed Plaintiff a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Patel was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Patel did not receive FDA warnings from Defendant.

e) Dr. Patel was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately May 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include trouble breathing, coughing, difficulty with exertion, shortness of breath, weakness, vision loss, tremors and fatigue. He was presented with a diagnosis of Amiodarone induced-pulmonary fibrosis and vision loss. Amiodarone-induced

pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary fibrosis and vision loss, Plaintiff was a remarkably healthy and active individual. After developing these injuries, he is often fatigued and short of breath and requires assistance with daily life activities. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

68. **Plaintiffs John Morris and Elizabeth Morris**

a) On personal knowledge, Plaintiff John Morris (hereinafter "Plaintiff" or "Morris") is an individual who resides in Maricopa County, Arizona. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed pulmonary fibrosis, which is a life-threatening and debilitating condition. In or around May 2011, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed pulmonary fibrosis and Amiodarone-induced lung toxicity, both serious and potentially deadly complications. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around January 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Paul Hass prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Paul Hass was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Hass did not receive FDA warnings from Defendant.

e) Dr. Hass was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately February 2014, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, coughing, wheezing, trouble breathing, coughing, respiratory failure, fatigue, weakness, edema, and difficulty with exertion. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Amiodarone-induced pulmonary fibrosis is a debilitating, chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after his diagnosis that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing pulmonary fibrosis and Amiodarone-induced pulmonary fibrosis, he was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary fibrosis, he could not walk across the room or exert himself. His condition deteriorated rapidly and he went into respiratory failure and a coma. He remained in a coma for six weeks and required intensive therapies. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) Additionally, Plaintiff, Elizabeth Morris is the spouse of the Plaintiff John Morris, and resides with her spouse, and she depended on John Morris to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff John Morris, Plaintiff Elizabeth Morris has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

69. **Plaintiffs Lonnie Myers and Barbara Myers**

a) On personal knowledge, Plaintiff Lonnie Myers (hereinafter “Plaintiff” or “Myers”) is an individual who resides in Montgomery County, Texas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity and respiratory failure, which is a life-threatening and debilitating condition. In or around February 2016, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary toxicity and respiratory failure, both serious and potentially deadly complications. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around February 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Amilcar

Avendano prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Amilcar Avendano was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Avendano did not receive FDA warnings from Defendant.

e) Dr. Avendano was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately April 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, and anemia. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity, respiratory failure and COPD. Amiodarone-induced pulmonary toxicity is a debilitating, chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after his diagnosis that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing Amiodarone-induced pulmonary toxicity and respiratory failure, he was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary toxicity and respiratory failure, he struggles to exert himself, frequently develops pneumonia and requires oxygen to breathe. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) Additionally, Plaintiff, Barbara Myers is the spouse of the Plaintiff Lonnie Myers, and resides with her spouse, and she depended on Lonnie Myers to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Lonnie Myers, Plaintiff Barbara Myers has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

70. **Plaintiffs Hans Omasta and Winona Omasta**

a) On personal knowledge, Plaintiff, Hans Omasta (hereinafter "Plaintiff" or "Omasta") is an individual who resides in Gilmer County, Georgia. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and impairment, a life-altering and debilitating condition. In August 2008, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, he developed Amiodarone-induced vision loss and impairment. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe

and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In August 2008, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Jimmie Dale Cannon prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Jimmie Dale Cannon was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Cannon did not receive FDA warnings from Defendant.

e) Dr. Cannon was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately September 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include impaired vision, spots before his

eyes and headaches. His optometrist diagnosed the retina deposit scars and vision loss as related to Amiodarone use and recommended that his cardiologist stop prescribing Amiodarone. The Amiodarone treatment was stopped.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing retinal deposit scars, also referred to as Amiodarone deposits, he was a remarkably healthy and active individual. He now cannot enjoy reading, watching television and everyday activities. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced vision loss.

i) Additionally, Plaintiff Winona Omasta is the spouse of the Plaintiff Hans Omasta and resides with her spouse, and she depended on Plaintiff Hans Omasta to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Hans Omasta, Plaintiff Winona Omasta has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

71. **Plaintiff Robert Perkins**

a) Plaintiff Robert Perkins (hereinafter "Plaintiff" or Perkins") is an individual who resides in Hamilton County, Ohio. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone induced pulmonary fibrosis, a life-threatening and debilitating condition. In November 2011, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his

Amiodarone use, he developed Amiodarone-induced respiratory failure, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In February 2012, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Mickelson prescribed Plaintiff a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Mickelson was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Mickelson did not receive FDA warnings from Defendant.

e) Dr. Mickelson was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately June 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, irregular heart rate, difficulty breathing, fatigue, weakness, anxiousness, depression, and elevated liver enzymes. In June of 2016, he had been admitted to the hospital with an initial diagnosis of atypical bilateral pneumonia, and chronic respiratory failure. The doctor treating him discontinued his use of Amiodarone. As his condition rapidly deteriorated, several high definition CT scans were performed, which revealed atypical interstitial pneumonia, diaphragm paralysis, pulmonary edema and hemorrhage, as well as airspace disease. After spending nearly two weeks in the hospital, including time in ICU requiring breathing assistance devices such as BiPap, or CPAP, as well as full time oxygen he was discharged with a diagnosis of chronic respiratory failure. His severe restrictive lung disease requires in-home nursing care, physical therapy, and the use of oxygen 24 hours per day, this condition limits his mobility and quality of life significantly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced respiratory failure, he was a very active and healthy individual. He spent a great deal of time enjoying his family members. He was a hard worker, employed full time as a bus driver for Hertz. After his discharge from the hospital, he has become disabled and required to leave his employment. He now struggles just to talk without losing his breath. He also suffers from a litany of other health problems related to his use of

Amiodarone, including left lung paralysis, heart failure, abnormal thyroid function, and abnormal liver enzymes.

72. **Plaintiff Lisa Pullen**

a) On personal knowledge, Plaintiff Lisa Pullen (hereinafter “Plaintiff” or “Pullen”) is an individual who resides in Morehouse Parish, Louisiana. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced thyroid disease and vision loss, life-altering and debilitating conditions. In or around November 2016 she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced thyroid disease and vision loss, serious and potentially life-threatening conditions. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In approximately November 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Young prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Young was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Young did not receive FDA warnings from Defendant.

e) Dr. Young was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately March 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include thyroid damage and vision loss, she has been hospitalized multiple times and required several thyroid surgeries and requires assistance in daily life activities. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced thyroid disease.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Prior to developing Amiodarone-induced thyroid disease and vision loss, Plaintiff was a remarkably healthy and active individual. After developing thyroid damage and vision loss, she has been hospitalized multiple times and required several thyroid surgeries and requires assistance in daily life activities. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced thyroid disease.

73. **Plaintiffs Richard Reed and Vicki Reed**

a) On personal knowledge, Plaintiff Richard Reed (hereinafter “Plaintiff” or “Reed”) is an individual who resides in Douglas County, Colorado. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced respiratory failure, which is a life-threatening and debilitating condition. In or around January 2016, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced respiratory failure, a serious and potentially deadly complication. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed

Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around January 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Vito Colandra prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Vito Colandra was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Colandra did not receive FDA warnings from Defendant.

e) Dr. Colandra was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately March 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include difficulty breathing, oxygen dependence, fatigue, weakness, irregular bleeding, vision complications and an irregular heartrate. After several hospital admissions and treatment for pneumonia, he was presented with a diagnosis of Chronic Respiratory Failure. Amiodarone-induced respiratory failure is a debilitating, chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced respiratory failure is extremely poor.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after his diagnosis that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing Amiodarone-induced respiratory failure, he enjoyed a normal and active lifestyle with his family. After developing Amiodarone-induced respiratory failure, he became oxygen dependent and now struggles to keep up with daily life activities. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced respiratory failure.

i) Additionally, Plaintiff, Vicki Reed is the spouse of the Plaintiff Richard Reed, and resides with her spouse, and she depended on Richard Reed to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Richard Reed, Plaintiff Vicki Reed has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

74. **Plaintiffs Sandra Rhodes and Charles Rhodes**

a) Plaintiff, Sandra Rhodes (hereinafter "Rhodes") is an individual who resides in Covington County, Alabama. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone, which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed respiratory failure, a life-threatening and debilitating condition. In November, 2011, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed respiratory failure, a serious and potentially deadly lung disease. She received no warning from her physician about these potential

life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around November 2011, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Peter Rao prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Peter Rao was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Rao did not receive FDA warnings from Defendant.

e) Dr. Rao was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial

fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately December, 2011, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. She was hospitalized in January 2011 for a surgical procedure and in that time, the results from her CT scans found bilateral pleural effusions and pneumonia in the right upper lobe and right lower lobe, as well as pulmonary hypertension. In 2012, a chest x-ray revealed cardiomegaly and scarring in the right upper lobe of her lung.

g) In March of 2013, due to the lack of Amiodarone’s efficacy for treatment of her a-fib, Dr. Rao discontinued her use of Amiodarone for suppression therapy. Later, in August 2013, Amiodarone therapy was once again re-initiated by Dr. Rao for treatment. Her symptoms continued to worsen including significant increase in fatigue, shortness of breath, hair loss, bruising and limited activity. Again, she was admitted to the hospital in July 2014. At this time, she was diagnosed with respiratory failure, and renal failure among other conditions and she was admitted for treatment. During another hospitalization in April of 2015, CT results were conclusive of scarring in the left lung base, as well as atherosclerotic calcifications found in the renal arteries.

h) In May 2015, she was admitted to the hospital for complications of respiratory failure. Both Dr. Rao and Dr. Sinclair discontinued her Amiodarone treatment after determining that she had drug-induced pneumonitis from Amiodarone and Pacerone.

i) In July of 2015, she was evaluated by an ophthalmologist for her vision complications, including decreased, troublesome vision, as well as discomfort where she was diagnosed with Amiodarone Keratopathy and bilateral corneal dystrophy, and cataracts.

j) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale

of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

k) Before developing Amiodarone toxicity, she enjoyed her life with her husband and family. She enjoyed traveling to visit family members and engaged in exercise to maintain a healthy lifestyle. She enjoyed crossword puzzles and reading as well. After developing respiratory failure, she struggles to enjoy the life she once knew with her family. In addition to kidney failure, respiratory failure and vision loss, she also lost her hair, gained weight, suffered severe bruising and bleeding and was very depressed.

l) Additionally, Plaintiff, Charles Rhodes, is the spouse of the Plaintiff Sandra Rhodes, and resides with his spouse, and he depended on Sandra Rhodes to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Sandra Rhodes, Plaintiff Charles Rhodes has in the past and will in the future suffer and incur loss of her consortium, loss of his spouse's services, the cost and expense of having medical care, attention and treatment for her, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

75. **Plaintiffs Bobbie Roberts and Troy Roberts**

a) On personal knowledge, Plaintiff Bobbie Roberts (hereinafter "Plaintiff" or "Roberts") is an individual who resides in San Augustine County, Texas. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced interstitial lung disease, vision loss, and thyroid disease, all severe and debilitating conditions. In approximately May 2013, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced interstitial lung disease, vision loss, and thyroid disease, all serious and debilitating diseases. She received no warning from her physician about these potential life-

threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around May 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Guniganti prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Guniganti was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Guniganti did not receive FDA warnings from Defendant.

e) Dr. Guniganti was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to

her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately February 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, difficulty breathing, coughing, vision loss, fatigue, weakness, nervousness and depression. She was presented with a diagnosis of Amiodarone-induced interstitial lung disease, vision loss, and hypothyroidism. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced interstitial lung disease is extremely poor. Amiodarone-induced interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced interstitial lung disease, vision loss, and hypothyroidism, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced interstitial lung disease, vision loss, and hypothyroidism, she suffers from frequent pneumonias, and struggles to exert herself as she used to. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced interstitial lung disease.

i) Additionally, Plaintiff Troy Roberts, is the spouse of the Plaintiff Bobbie Roberts, and resides with his spouse, and he depended on Bobbie Roberts to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Bobbie Roberts, Plaintiff Troy Roberts has in the past and will in the future suffer and

incur loss of her consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

76. **Plaintiff Larry E. Robinson**

a) On personal knowledge, Larry Robinson (hereinafter "Plaintiff" or "Robinson") is an individual who resides in Jackson County, Indiana. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone, which was manufactured, promoted, supplied and/or distributed by Defendants. In August 2014, he was diagnosed as suffering from A-fib, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed hyperthyroidism, a serious life altering disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for "off-label" use by them.

d) In or around October 2014, as a result of the long term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Richard Martin prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Martin was a victim of Defendant Wyeth's long term and successful promotional efforts as well as Zydus and potentially other manufacturers' sales efforts that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Martin did not receive FDA warnings from Defendant.

e) Dr. Martin was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately October 2016, Plaintiff began to experience shortness of breath, coughing, nausea, abdominal discomfort, abnormal weight loss, fatigue, weakness, limited exertion, restlessness, abnormal heart rate, and depression. He was presented with a diagnosis of hyperthyroidism. Hyperthyroidism is a debilitating chronic condition that can significantly impact quality of life.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, only later did he become aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced hyperthyroidism, Plaintiff was a remarkably healthy and active individual. He enjoyed regular exercise, working in construction, being outdoors, and spending quality time with his family. After developing hyperthyroidism, he struggled to be active and maintain his prior lifestyle. He also started to experience a thyrotoxicosis or thyroid storm, resulting in physical discomfort and requiring medical treatment. He also lost weight and suffers from a litany of other health problems related to his use of Amiodarone.

77. **Plaintiff Lois Roncal**

a) On personal knowledge, Plaintiff Lois Roncal (hereinafter "Plaintiff" or "Roncal") is an individual who resides in Smith County, Texas. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision injury and loss, a life-altering and debilitating condition. In or around April 2015, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced vision injury and loss, a serious and potentially disabling condition. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative

to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them, and which was distributed nationwide by McKesson.

d) In April 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Roderick Meese prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Roderick Meese was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Meese did not receive FDA warnings from Defendant.

e) Dr. Meese was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately December 2015, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include vision loss, eye pain, floaters, loss of visual acuity, trouble with coordination due to vision loss, corneal damage and ulcers, trouble breathing, coughing, and fatigue. She was presented with a diagnosis of Amiodarone vision injury and loss including corneal ulcers and damage. In addition, she suffered pulmonary injury and difficulty breathing because of her Amiodarone use. Amiodarone-induced vision loss is a debilitating condition that could worsen over time resulting in other visual complications. Amiodarone-induced vision loss injury and loss often cannot be corrected and causes a significant impairment on quality of life.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing vision injury and loss and pulmonary complications, Plaintiff was a remarkably healthy and active individual. After developing these injuries, she could not easily read or drive and she was often fatigued and short of breath. She also and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced vision injury and pulmonary injury.

78. **Plaintiff Jimmie Ross**

a) On personal knowledge, Plaintiff Jimmie Ross (hereinafter "Plaintiff" or "Ross") is an individual who resides in Ouachita Parish, Louisiana. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced thyroid disease, kidney injury and vision loss, all life-threatening and debilitating conditions. In or around October 2017, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be

Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced thyroid toxicity, kidney injury and Amiodarone-induced optic neuropathy resulting in total blindness. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In October 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Mouhaffell prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Mouhaffell was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Mouhaffell did not receive FDA warnings from Defendant.

e) Dr. Mouhaffell was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately February 2018, he began to experience many of the symptoms outlined in the FDA labeling which include total vision loss (legally blind), thyroid disease, kidney damage, dizziness, weakness, and poor coordination due to loss of vision. He was presented with a diagnosis of Amiodarone-induced optic neuropathy resulting in total blindness. Amiodarone-induced optic nerve damage and blindness is a debilitating, chronic, progressive condition that does not improve over time resulting in significant disability and impaired quality of life.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced thyroid disease, kidney injury, and Amiodarone-induced vision loss, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced complications, he can no longer read or drive and requires assistance with daily life activities. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced injuries

79. **Plaintiff Karen Roth**

a) On personal knowledge, Plaintiff Karen Roth, Personal Representative of the Estate of Doris Hildebrand, deceased, (hereinafter "Plaintiff" or "Hildebrand") is an individual who resides in Gwinnett County, Georgia. Ms. Hildebrand was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause

thereof, developed Amiodarone-induced pulmonary toxicity and interstitial lung disease, both life-threatening and debilitating conditions. In April 2016, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. Her cardiologist prescribed her a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary toxicity and interstitial lung disease, serious and potentially deadly lung diseases. She received no warning from her physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around October 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Shalini Modi prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Shalini Modi was a victim of the long-term and

successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Modi did not receive FDA warnings from Defendant.

e) Dr. Modi was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately January 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, and chest pain. She was presented with a diagnosis of Amiodarone-induced pulmonary toxicity and interstitial lung disease. Amiodarone-induced pulmonary toxicity and interstitial lung disease are debilitating chronic, progressive conditions that only worsen over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity and interstitial lung disease is extremely poor. Amiodarone-induced pulmonary toxicity and interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary toxicity and interstitial lung disease, Ms. Hildebrand was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary toxicity and interstitial lung disease, she could not walk across the room, was often weak and short of breath. She also suffered from a litany of other health

problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary toxicity and interstitial lung disease.

i) After developing Amiodarone-induced pulmonary toxicity and interstitial lung disease, her condition deteriorated rapidly, requiring hospitalization. She could not adequately breathe on her own, requiring breathing assistance and oxygen use. After spending three weeks in the hospital, Doris Hildebrand succumbed to her Amiodarone-induced pulmonary toxicity, interstitial lung disease and respiratory failure on May 24, 2017.

80. **Plaintiff Richard Ryan**

a) On personal knowledge, Plaintiff Richard Ryan (hereinafter “Plaintiff” or “Ryan”) is an individual who resides in Brown County, Wisconsin. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injury and respiratory failure, which is a life-threatening and debilitating condition. In or around July 2012, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary toxicity and respiratory failure, both serious and potentially deadly complications. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around October 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Zhaowei Ai prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Zhaowei Ai was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Ai did not receive FDA warnings from Defendant.

e) Dr. Ai was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately January 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, abnormal bleeding, and abnormal kidney function. He was presented with a diagnosis of Amiodarone-induced pulmonary injury and respiratory failure. Amiodarone-induced pulmonary injury and respiratory failure are debilitating, chronic, progressive conditions that only worsen over time. The five-year survival rate for individuals with

Amiodarone-induced pulmonary injury and respiratory failure is extremely poor. Amiodarone-induced pulmonary injury and respiratory failure cause the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after his diagnosis that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing Amiodarone-induced pulmonary injury and respiratory failure, he was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary injury and respiratory failure, his health deteriorated rapidly and he required the use of oxygen and pulmonary rehab for over a month. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary injuries.

81. **Plaintiff Mohammad Saleem**

a) On personal knowledge, Plaintiff Mohammad Saleem (hereinafter "Plaintiff" or "Saleem") is an individual who resides in Winnebago County, Illinois. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed vision loss from Amiodarone toxicity, a life-altering and debilitating condition. In or around June 2016, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed vision loss from Amiodarone. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In June 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Donald Rabor prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Donald Rabor was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Rabor did not receive FDA warnings from Defendant.

e) Dr. Rabor was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately August 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include vision loss, visual disturbances, double vision, dizziness and trouble with coordination due to vision loss. He was presented with a diagnosis of Amiodarone-induced vision injury/oss in both eyes. Amiodarone-induced vision loss is a debilitating condition that worsens over time, resulting in other visual complications. Amiodarone-induced vision loss/injury often cannot be corrected and causes a significant impairment on quality of life.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone toxicity, he was a remarkably healthy and active individual. After developing Amiodarone-induced vision loss/injury, he could not easily read or drive. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced vision loss/injury.

82. **Plaintiff Albert Shepherd**

a) On personal knowledge, Albert Shepherd, Personal Representative of the Estate of Emily Shepherd, deceased (hereinafter "Plaintiff" or "Shepherd") is an individual who resides in Starke County, Indiana. Mrs. Shepherd was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating pulmonary condition. In October 2011, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis and respiratory failure, serious and potentially deadly lung diseases. She received no warning from her physician about

these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around October 2011, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Rishi Sukhija prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Rishi Sukhija was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Sukhija did not receive FDA warnings from Defendant.

e) Dr. Sukhija was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial

fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately May 2015, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, edema, tremors, dizziness, and weakness. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis and respiratory failure. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) Plaintiff was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis and respiratory failure, Plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis, she could not walk across the room and required oxygen. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis and respiratory failure.

i) After developing pulmonary fibrosis and respiratory fibrosis her condition deteriorated rapidly, requiring hospitalization. She could not adequately breathe on her own, requiring breathing assistance and oxygen use. After spending several days in the hospital, Emily Shepherd succumbed to her Amiodarone-induced pulmonary fibrosis and respiratory failure on October 8, 2016.

83. **Plaintiffs Cynthia Skiles and Raymond Skiles**

a) On personal knowledge, Plaintiff Cynthia Skiles (hereinafter “Plaintiff” or “Skiles”) is an individual who resides in Armstrong County, Pennsylvania. She was prescribed,

purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, a life-threatening and debilitating condition. In or around February 2013, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary toxicity, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for "off-label" use by them.

d) In February 2013 as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Marvin Baker prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and

potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Marvin Baker was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Baker did not receive FDA warnings from Defendant.

e) Dr. Baker was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately February 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, coughing, weakness, edema, dizziness, chest pain, and fatigue. She was presented with a diagnosis of pulmonary toxicity. Pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary toxicity is extremely poor. Pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary toxicity, she was a remarkably healthy and active individual. After developing pulmonary fibrosis, she is often fatigued and short of breath and requires assistance with daily life activities. She also suffers from a litany of other

health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary toxicity.

i) Additionally, Plaintiff, Raymond Skiles is the spouse of the Plaintiff Cynthia Skiles, and resides with his spouse, and he depended on Cynthia Skiles to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Cynthia Skiles, Plaintiff Raymond Skiles has in the past and will in the future suffer and incur loss of her consortium, loss of his spouse's services, the cost and expense of having medical care, attention and treatment for her, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

84. **Plaintiff Jeanette Smith-Akyol**

a) On personal knowledge, Plaintiff Jeanette Smith-Akyol (hereinafter "Plaintiff" or "Smith-Akyol") is an individual who resides in Volusia County, Florida. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and deterioration. In or around February 2016, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed vision loss and other vision complications from Amiodarone toxicity. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, here doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians

of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In March 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Rajendra G. Hippalgaonka prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Rajendra G. Hippalgaonka was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Hippalgaonka did not receive FDA warnings from Defendant.

e) Dr. Hippalgaonka was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and her prescription was for an “off-label” use.

f) Beginning in approximately March 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include vision loss, multiple vision complications, coughing, tiredness, muscle pain, difficulty with movement and exertion, skin rashes and blisters,

and weakness. Her vision is now blurry and has limited her ability to maintain her previous lifestyle

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced vision loss and deterioration, she was a remarkably healthy and active individual. After developing Amiodarone-induced vision loss and deterioration, she struggles to enjoy her normal activities. She also suffers from a litany of other health problems related to her use of Amiodarone.

85. **Plaintiff Ieda Sturgill**

a) On personal knowledge, Plaintiff Ieda Sturgill (hereinafter "Plaintiff" or "Sturgill") is an individual who resides in Montgomery County, Virginia. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease, liver and thyroid damage, all life-altering, severe and debilitating vision conditions. In approximately March 2010, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary disease, liver and thyroid damage, all serious and debilitating diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative

to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around March 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Soufian Almahameed prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Soufian Almahameed was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Almahameed did not receive FDA warnings from Defendant.

e) Dr. Almahameed was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately March 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which includes shortness of breath, wheezing, trouble

breathing, coughing, fatigue, chest pain, weakness, abdominal pain, abnormal liver and thyroid function. She was presented with a diagnosis of Amiodarone-induced interstitial lung disease and thyroid and liver injury. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced interstitial lung disease is extremely poor. Amiodarone-induced interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced interstitial lung disease, liver and thyroid injuries, Plaintiff was a remarkably healthy and active person who enjoyed spending time with her family. After developing Amiodarone-induced interstitial lung disease, she was often weak, fatigued and short of breath. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmongy, liver and thyroid injuries.

86. **Plaintiff Brian Sukenik**

a) On personal knowledge, Plaintiff Brian Sukenik (hereinafter "Plaintiff" or "Sukenik") is an individual who resides in Cambria County, Pennsylvania. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Zydus and potentially other manufacturers and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, a life-threatening and debilitating condition. In March 2014, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced

pulmonary toxicity, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In April 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Cyril Nathaniel prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Cyril Nathaniel was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Nathaniel did not receive FDA warnings from Defendant.

e) Dr. Nathaniel was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately October 2015, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, dizziness, chest pain, skin lesions/growths, memory loss, abnormal bleeding and bruising, edema, coughing, fatigue, weakness, and increased anxiety. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary toxicity, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary toxicity, he struggled to exert himself, required a CPAP machine for breathing assistance, and both his liver and kidney function declined. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity including congestive heart failure, anemia, skin lesions/growths, abnormal liver function and kidney disease.

87. **Plaintiff Georgia Sutton**

a) On personal knowledge, Plaintiff Georgia Sutton (hereinafter “Plaintiff” or “Sutton”) is an individual who resides in New Castle County, Delaware. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around June 2009, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced interstitial lung disease, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around June 2009, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because they did not receive FDA

warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Paul Alfieiri and Dr. Kenneth Corrine prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Paul Alfieiri and Dr. Kenneth Corrine were victims of Wyeth's long-term and successful promotional efforts as well as Zydus and potentially other manufacturers' marketing and sales efforts that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Alfieri and Dr. Corrine did not receive FDA warnings from Defendant.

e) Dr. Alfieri and Dr. Corrine were not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately June 2015, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, chest pain, fainting, edema, and irregular heart rate. She was presented with a diagnosis of Amiodarone-induced interstitial lung disease. Interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing interstitial lung disease, she was a remarkably healthy and active individual. After developing interstitial lung disease, she struggled to exert herself and was often fatigued. She also and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced vision injury and pulmonary injury.

88. **Plaintiff William Teesch**

a) On personal knowledge, Plaintiff William Teesch (hereinafter “Plaintiff” or “Teesch”) is an individual who resides in Manitowoc County, Wisconsin. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, kidney injury and vision loss, all life-threatening and debilitating conditions. In or around April 2017, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary toxicity, kidney injury, as well as vision loss. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed

Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In April 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Matthias Fuchs prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Matthias Fuchs was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Fuchs did not receive FDA warnings from Defendant.

e) Dr. Fuchs was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately September 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, vision loss, loss of visual acuity, trouble with coordination, abdominal pain, tremors, nausea, hair loss, trouble breathing, coughing and fatigue. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity, impaired kidney function, and vision loss. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened,

making it difficult for lungs to work properly. In addition to Amiodarone-induced pulmonary toxicity, he was also diagnosed with Amiodarone-induced kidney injury and vision loss.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary toxicity, kidney injury and vision loss, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary toxicity, kidney injury and vision loss, he now struggles to exert himself, and he cannot easily read or drive, and is often fatigued and short of breath. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary, vision and kidney injuries.

89. **Plaintiffs Cecil Thomas and Debbie Thomas**

a) On personal knowledge, Plaintiff Cecil Thomas (hereinafter "Plaintiff" or "Thomas") is an individual who resides in Union County, North Carolina. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss, life-threatening and debilitating conditions. In February 2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced total vision loss, a serious and permanently disabling blindness due to ischemic optic neuropathy. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In February 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Glen Fandetti prescribed him a course of 400mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Glen Fandetti was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Fandetti did not receive FDA warnings from Defendant.

e) Dr. Fandetti was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately June 2015, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include vision and vision loss, blindness, headaches, poor coordination, and dizziness. He was presented with a diagnosis of Amiodarone-induced ischemic optic neuropathy in both eyes, causing total blindness. Amiodarone-induced blindness is a debilitating chronic condition that is unlikely to improve resulting in significant disability.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing Amiodarone-induced blindness, Plaintiff was a remarkably healthy and active individual. After developing vision loss, he could no longer work, drive or read, and requires full time assistance with daily life activities. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced optic injury.

i) Additionally, Plaintiff Debbie Thomas is the spouse of the Plaintiff Cecil Thomas, and resides with her spouse, and she depended on Cecil Thomas to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Cecil Thomas, Plaintiff Debbie Thomas has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

90. **Plaintiff John Nathan Timm**

a) On personal knowledge, Plaintiff John Nathan Timm (hereinafter "Plaintiff" or "Timm") is an individual who resides in Flathead County, Montana. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause

thereof, developed Amiodarone-induced interstitial lung disease, a life-threatening and debilitating condition. In or around 2011, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced interstitial lung disease, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In April 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Robert Mitchell prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Robert Mitchell was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use

for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Mitchell did not receive FDA warnings from Defendant.

e) Dr. Mitchell was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately May 2016, he began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, weight gain, joint pain, and difficulty with exertion. After frequent admissions to the hospital and suffering several pneumonias, he was presented with a diagnosis of Amiodarone-induced interstitial lung disease. Interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing interstitial lung disease, Plaintiff was a remarkably healthy and active individual. After developing interstitial lung disease, he could barely walk across the room and required the use of a CPAP machine for breathing assistance. He also gained weight and suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced interstitial lung disease.

91. **Plaintiffs Laurel Turley and Roger Turley**

a) On personal knowledge, Plaintiff Laurel Turley (hereinafter “Plaintiff” or “Turley”) is an individual who resides in Belmont County, Ohio. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease and thyroid disease, both life-threatening and debilitating condition. In or around June 2012, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In June 2012 as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because she did not receive FDA warnings as a

result of Defendant's failure to adequately communicate such warnings, Dr. Adele Frenn prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Frenn was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Frenn did not receive FDA warnings from Defendant.

e) Dr. Frenn was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately 2015, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, chest pain, edema, and abnormal thyroid function. She was presented with a diagnosis of Amiodarone-induced interstitial lung disease and hypothyroidism. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced lung disease and thyroid toxicity, she was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary disease and hypothyroidism, she struggles to exert herself and is often weak and short of breath. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary disease and hypothyroidism.

i) Additionally, Plaintiff, Roger Turley is the spouse of the Plaintiff Laurel Turley, and resides with his spouse, and he depended on Laurel Turley to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Laurel Turley, Plaintiff Roger Turley has in the past and will in the future suffer and incur loss of her consortium, loss of his spouse's services, the cost and expense of having medical care, attention and treatment for her, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

92. **Plaintiff Doyle Turner**

a) On personal knowledge, Doyle Turner, Individually and as Personal Representative of the Estate of Carolyn Turner, deceased (hereinafter "Plaintiff" or "Turner") is an individual who resides in Gregg County, Texas. Mrs. Turner was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute interstitial lung disease, a life-threatening and debilitating condition. In or around October 2014, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced interstitial lung disease and respiratory failure, both serious and potentially deadly lung diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In October 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Gordon Uretsky prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Gordon Uretsky was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Uretsky did not receive FDA warnings from Defendant.

e) Dr. Uretsky was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its

bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately April 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include vision loss, blurry vision, trouble with coordination due to vision loss, hallucinations and overall weakness, as well as shortness of breath, wheezing, difficulty breathing, coughing, fatigue, and weakness. She was presented with a diagnosis of Amiodarone-induced respiratory failure. Respiratory failure is a debilitating chronic, progressive condition that only worsens over time.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing vision loss and respiratory failure, Plaintiff was a remarkably healthy and active individual. After developing vision loss and respiratory failure, she could no longer enjoy many of the things she used to. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced respiratory failure.

i) After developing respiratory failure, her condition deteriorated rapidly, requiring extended hospitalization. She could not adequately breathe on her own, requiring breathing assistance and oxygen use. Carolyn Turner succumbed to her Amiodarone-induced respiratory failure on April 20, 2017.

93. **Plaintiff Pamela Upton**

a) On personal knowledge, Pamela Upton, Personal Representative of the Estate of Janice Covington, deceased (hereinafter “Plaintiff” or “Covington”) is an individual who resides in Rankin County, Mississippi. Mrs. Covington was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed

Amiodarone-induced acute pulmonary disease, renal failure, and vision loss, a life-threatening and debilitating condition. In or around March 2016, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary disease, renal failure, and vision loss, all serious and potentially deadly diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around March 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. McMullan prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. McMullan was a victim of the long-term and successful

promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. McMullan did not receive FDA warnings from Defendant.

e) Dr. McMullan was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately April 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, and exhaustion. She was presented with a diagnosis of Amiodarone-induced pulmonary disease and respiratory failure, vision loss, and kidney failure. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary disease, kidney failure, and vision loss Plaintiff was a remarkably healthy and active individual. After developing these complications, she could not walk across the room and suffered frequent pneumonias. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary disease including respiratory failure.

i) After developing kidney failure, vision loss, and respiratory failure her condition deteriorated rapidly, requiring hospitalization. She could not adequately breathe on her own, requiring oxygen use, also resulting in kidney failure. After spending several days in the hospital, Janice Covington succumbed to her Amiodarone-induced pulmonary disease, respiratory failure, and kidney failure on June 7, 2017.

94. **Plaintiff Martha Vernon**

a) On personal knowledge, Plaintiff Martha Vernon (hereinafter “Plaintiff” or “Vernon”) is an individual who resides in Hendricks County, Indiana. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injury including COPD, thyroid disease, and vision loss, all life-threatening and debilitating conditions. In or around January 2010 she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary injury, including COPD, a serious and potentially deadly lung disease. She also developed Amiodarone-induced hypothyroidism and vision loss. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) During 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because she did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Nancy Branyas prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Nancy Branyas was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Branyas did not receive FDA warnings from Defendant.

e) Dr. Branyas was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately December 2015, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, vision loss, abnormal thyroid function, weakness, and difficulty with exertion. She was presented with a diagnosis of Amiodarone-induced pulmonary injury, including COPD, vision loss and hypothyroidism. These are all debilitating chronic, progressive conditions that only worsen over time. The long-term survival rate for individuals

with this multitude of complications is extremely poor. COPD causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary, Plaintiff was a remarkably healthy and active individual who regularly exercised. After developing these injuries, she struggled to exert herself, could no longer drive at night, required cataracts surgery and was often fatigued. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary injury, COPD, vision loss and hypothyroidism.

95. **Plaintiff George Viola**

a) On personal knowledge, Plaintiff George Viola (hereinafter "Plaintiff" or "Viola") is an individual who resides in Osceola County, Florida. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, which is a life-threatening and debilitating condition. In or around March 2018, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary toxicity, a serious and potentially deadly complication. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around March 2018, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Husain prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Husain was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Husain did not receive FDA warnings from Defendant.

e) Dr. Husain was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately May 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include chest pain, coughing, heart palpitations, numbness, weakness, difficulty breathing and fatigue. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary toxicity is a debilitating, chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after his diagnosis that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing Amiodarone-induced pulmonary toxicity, he was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary toxicity, he is often fatigued and short of breath. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity.

96. **Plaintiff Mary Waters**

a) On personal knowledge, Plaintiff Mary Waters (hereinafter "Plaintiff" or "Waters") is an individual who resides in Beaufort County, North Carolina. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Zydus and potentially other manufacturers and as a proximate cause thereof, developed Amiodarone-induced interstitial lung disease, a life-threatening and debilitating condition. In or around August 2011, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced

interstitial lung disease, a serious and potentially deadly pulmonary disease. In addition to lung disease, she also suffered vision injuries, including glaucoma and cataracts. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around June 2012, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Jerry Simpson prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Jerry Simpson was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to

prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Simpson did not receive FDA warnings from Defendant.

e) Dr. Simpson was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately December 2015, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, trouble breathing, coughing, fatigue, weakness, vision loss and injury including cataracts and glaucoma, and difficulty with exertion. She was presented with a diagnosis of interstitial lung disease. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with interstitial lung disease is extremely poor. Amiodarone-induced interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly. She also suffered vision impairment due to her Amiodarone-induced cataracts and glaucoma, making it difficult to see clearly as she once did.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing interstitial lung disease, Plaintiff was a remarkably healthy and active individual. After developing interstitial lung disease and vision loss, she struggled to perform regular life activities such as exercise, walking, and reading. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone induced interstitial lung disease and vision impairment.

97. **Plaintiffs Stewart Wilkins and Mary Wilkins**

a) On personal knowledge, Plaintiff Stewart Wilkins (hereinafter “Plaintiff” or “Wilkins”) is an individual who resides in Wood County, Ohio. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed pulmonary fibrosis and respiratory failure, life-threatening and debilitating conditions. In or around September 2016, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis and respiratory failure, both serious and potentially deadly complications. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around September 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr.

Raj L. Bhatia prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Raj L. Bhatia was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Bhatia did not receive FDA warnings from Defendant.

e) Dr. Bhatia was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately March 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, blurry vision and depression. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis and respiratory failure. Amiodarone-induced pulmonary fibrosis is a debilitating, chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after his diagnosis that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary fibrosis and respiratory failure, he was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary fibrosis and respiratory failure, he is often short of breath, weak and unable to exert himself. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis and respiratory failure.

i) Additionally, Plaintiff, Mary Wilkins is the spouse of the Plaintiff Stewart Wilkins, and resides with her spouse, and she depended on Stewart Wilkins to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Stewart Wilkins, Plaintiff Mary Wilkins has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

98. **Plaintiffs Nancy Williams and Jim Williams**

a) On personal knowledge, Plaintiff Nancy Williams (hereinafter "Plaintiff" or "Williams") is an individual who resides in Sedgwick County, Kansas. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, a life-threatening and debilitating condition. In approximately December 2015, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary toxicity, a serious and debilitating condition. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe

and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around December 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Abid Mallick prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Abid Mallick was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Mallick did not receive FDA warnings from Defendant.

e) Dr. Mallick was not aware that Plaintiff’s use of the medication was for an “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, coughing, wheezing, trouble breathing, fatigue, chest pain, dizziness, weakness, and difficulty with exertion. She was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary injury is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary toxicity, Plaintiff was a remarkably healthy and active person who enjoyed spending time with her family. After developing Amiodarone-induced pulmonary toxicity, she struggles to exert herself and to enjoy the things she once did. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary toxicity.

i) Additionally, Plaintiff Jim Williams, is the spouse of the Plaintiff Nancy Williams, and resides with his spouse, and he depended on Nancy Williams to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Nancy Williams, Plaintiff Jim Williams has in the past and will in the future suffer and incur loss of her consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

99. **Plaintiffs Katherine Wollaston and Daniel Wollaston**

a) On personal knowledge, Plaintiff Katherine Wollaston (hereinafter "Plaintiff" or "Wollaston") is an individual who resides in Chautauqua County, New York. She was prescribed,

purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary injury and kidney disease, life-threatening and debilitating conditions. In or around April 2003, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary injury and kidney disease, both serious and potentially deadly diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around October 2003, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because they did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Jeffrey Dakas and Dr. Kelly Hayes prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone

manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Jeffrey Dakas and Dr. Kelly Hayes were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Dakas and Dr. Hayes did not receive FDA warnings from Defendant.

e) Dr. Dakas and Dr. Hayes were not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately April 2015, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble with exertion, coughing, fatigue, kidney disease, weakness, weight fluctuations, increased anxiety, and oxygen dependence. She was presented with a diagnosis of kidney disease and pulmonary injury including pulmonary hypertension, and restrictive lung disease. Pulmonary injury and pulmonary hypertension are debilitating chronic, progressive conditions that only worsen over time. The survival rate for individuals with Amiodarone-induced pulmonary injury, pulmonary hypertension and kidney disease is extremely poor. Restrictive pulmonary disease and pulmonary hypertension cause the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing her Amiodarone-induced pulmonary and kidney injuries, Plaintiff was a remarkably healthy and active individual. After developing restrictive pulmonary injury and pulmonary hypertension, she struggles to walk across the room and breathe comfortably. Her lung injuries have caused her to be oxygen dependent and she relies on the use of a BiPap and CPAP machine to assist in her breathing. She also suffers weight fluctuations and has significant difficulty sleeping due to her kidney and lung disease. She suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced restrictive pulmonary disease.

i) Additionally, Plaintiff Daniel Wollaston is the spouse of the Plaintiff Katherine Wollaston, and resides with his spouse, and he depended on Katherine Wollaston to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Katherine Wollaston, Plaintiff Daniel Wollaston has in the past and will in the future suffer and incur loss of his consortium, loss of his spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

100. **Plaintiffs James Mason and Cathy Mason**

a) On personal knowledge, Plaintiff James Mason (hereinafter "Plaintiff" or "Mason") is an individual who resides in Llano County, Texas. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis and vision loss, both life-altering and debilitating conditions. In or around January 2006, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a potentially life-threatening pulmonary disease, and vision loss. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that

Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around January 2006, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because they did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Muse and Dr. McCarland prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Muse and Dr. McCarland were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Muse and Dr. McCarland did not receive FDA warnings from Defendant.

e) Dr. Muse and Mr. McCarland were not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of

Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately October 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include trouble breathing, shortness of breath, coughing, wheezing, weakness, dizziness, chest pain, vision loss and fatigue. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis and vision loss. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive lung condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing Amiodarone-induced pulmonary fibrosis and vision loss, Plaintiff was a healthy and very active individual. After developing Amiodarone-induced pulmonary fibrosis, he struggles to exert himself and is often short of breath. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) Additionally, Plaintiff Cathy Mason is the spouse of the Plaintiff James Mason, and resides with her spouse, and she depended on James Mason to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff James Mason, Plaintiff Cathy Mason has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse’s services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

101. **Plaintiff Jacqueline Fabbri**

a) On personal knowledge, Jacqueline Fabbri, Personal Representative of the Estate of Frank Fabbri, deceased (hereinafter “Plaintiff” or “Fabbri”) is an individual who resides in San Luis Obispo County, California. Mr. Fabbri was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary fibrosis, a life-threatening and debilitating condition. In October 2015, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In October 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because she did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Lorianna Fletcher

prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Lorianna Fletcher was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Fletcher did not receive FDA warnings from Defendant.

e) Dr. Fletcher was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately July 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue and weakness. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis, he could not walk across the room and

suffered frequent pneumonias. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) After developing pulmonary fibrosis, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring breathing assistance and oxygen use. After spending several days in the hospital, Frank Fabbri succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on September 6, 2016.

102. Plaintiffs Robert Kizanis and Velomy Kizanis

a) On personal knowledge, Plaintiff Robert Kizanis (hereinafter “Plaintiff” or “Kizanis”) is an individual who resides in Orange County, California. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss, a life-altering and debilitating condition. In or around January 2016, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced vision loss and injury, including an eye stroke and total loss of vision in one eye. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed

Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In January 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Teferi Mitiku prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Teferi Mitiku was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Mitiku did not receive FDA warnings from Defendant.

e) Dr. Mitiku was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately September 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include decreased visual acuity, blurry vision, dizziness, fatigue, poor coordination, weakness, and sudden vision loss to his left eye. He was presented with a diagnosis of Amiodarone-induced vision loss from a left eye stroke resulting in total vision loss in one eye and decreased vision in the other eye. Amiodarone-induced vision loss is a debilitating, chronic, progressive condition that does not improve over time resulting in significant disability and impaired quality of life. Often the optic damage significantly impairs quality of life and cannot be reversed.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced vision loss, Plaintiff was a remarkably healthy and active individual. He enjoyed spending time with his family and surfing. After developing Amiodarone-induced vision loss, he struggles to independently perform the tasks of daily life and struggles to read, drive and enjoy television. He also suffers from a litany of other health problems related to his use of Amiodarone.

i) Additionally, Plaintiff, Velomy Kizanis, is the spouse of the Plaintiff Robert Kizanis, and resides with her spouse, and she depended on Robert Kizanis to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Robert Kizanis, Plaintiff Velomy Kizanis has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

103. **Plaintiff Carletta Williams**

a) Carletta Williams, individually and as Personal Representative of the Estate of James C. Williams, III, deceased (hereinafter "Williams") is an individual who resides in Lucas County, Ohio. Mr. Williams was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone induced pulmonary disease and vision loss, both serious and potentially disabling conditions. In or around 2010, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary disease and vision loss, both serious and potentially

debilitating conditions. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Paul Berlacher prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Berlacher was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Berlacher did not receive FDA warnings from Defendant.

e) Dr. Berlacher was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to

his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately 2012, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, blurred vision, vision loss, and weakness. He was presented with a diagnosis of Amiodarone-induced pulmonary disease and vision loss. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary disease is extremely poor. Pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Prior to developing Amiodarone-induced pulmonary disease and vision loss, Plaintiff was a remarkably healthy and active individual. After developing pulmonary disease and vision loss, he struggled to exert himself and was often short of breath and fatigued. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary disease and vision loss.

i) After developing pulmonary disease and vision loss, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring breathing assistance and oxygen use. After spending significant time in the hospital, James C. Williams, III succumbed to his Amiodarone-induced pulmonary disease and respiratory failure on February 7, 2017.

104. **Plaintiff Elmo Wayne Duncan**

a) On personal knowledge, Plaintiff Elmo Wayne Duncan (hereinafter "Plaintiff" or "Duncan") is an individual who resides in Marshall County, Alabama. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis and vision loss, both life-threatening and debilitating conditions. In or around September 2014, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis and vision loss, serious and potentially disabling conditions. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for "off-label" use by them.

d) In September 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Evan Cohen

prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Evan Cohen was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Cohen did not receive FDA warnings from Defendant.

e) Dr. Cohen was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately November 2014, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include burning in his eyes, loss of vision, sores that do not heal on his nose, exertion, shortness of breath, wheezing, coughing, tiredness, weakness, high blood pressure and depression. He was presented with a diagnosis of conea conjunctivea and vision loss as well as pulmonary issues. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary fibrosis and vision loss, Plaintiff was a remarkably healthy and active individual. After developing these injuries, he is often fatigued and short of breath and requires assistance with daily life activities. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

105. **Plaintiffs John Blackford and Maxine Blackford**

a) On personal knowledge, Plaintiff John Blackford (hereinafter “Plaintiff” or “Blackford”) is an individual who resides in Sonoma County, California. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and vision deterioration, a life-altering and debilitating condition. In or around February 2016, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced vision loss, as well as vision deterioration. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In February 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Joel Erickson prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Joel Erickson was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Erickson did not receive FDA warnings from Defendant.

e) Dr. Erickson was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately March 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include vision loss, including peripheral vision loss and depth perception loss, dizziness, shortness of breath, coughing, tiredness, weakness, nervousness, mood swings, severe irritability, restlessness, decreased concentration and depression. He was presented with a diagnosis of Amiodarone-induced vision loss and deterioration, as well as decreased peripheral and depth perception. This debilitating and irreversible diagnosis does not improve over time and drastically alters quality of life.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale

of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced ischemic optic neuropathy resulting in blindness, plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced blindness, he can no longer read or drive and requires assistance with daily life activities. He also suffers from a litany of other health problems related to his use of Amiodarone.

i) Additionally, Plaintiff, Maxine Blackwell, is the spouse of the Plaintiff John Blackwell, and resides with her spouse, and she depended on John Blackwell to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff John Blackwell, Plaintiff Maxine Blackwell has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

106. **Plaintiff Darlene Glasgow**

a) On personal knowledge, Plaintiff Darlene Glasgow, Personal Representative of the Estate of Kenneth Glasgow, deceased, (hereinafter "Plaintiff" or "Glasgow") is an individual who resides in San Luis Obispo County, California. Mr. Glasgow was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced interstitial lung disease, a life-threatening and debilitating condition. In December 2015, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a "rhythm medication," which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced interstitial lung disease, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around December 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Andrew Dennish prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Andrew Dennish was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Dennish did not receive FDA warnings from Defendant.

e) Dr. Dennish was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately May 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, abnormal bleeding, and dizziness. He was presented with a diagnosis of Amiodarone-induced interstitial lung. Interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced interstitial lung disease is extremely poor. Interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced interstitial lung disease, Mr. Glasgow was a healthy and active individual. He enjoyed spending regular walks and quality time with his family. After developing Amiodarone-induced interstitial lung disease, he struggled to exert himself and was debilitated with weakness and shortness of breath. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced interstitial lung disease.

i) After developing Amiodarone-induced interstitial lung diseases, his condition deteriorated rapidly, requiring hospitalizations. He could not adequately breathe on his own, requiring breathing assistance and oxygen. Kenneth Glasgow succumbed to his Amiodarone-induced interstitial lung disease on May 30, 2016.

107. **Plaintiffs Dianne Cruce and Doug Hyak**

a) On personal knowledge, Plaintiff Dianne Cruce (hereinafter "Plaintiff" or "Cruce") is an individual who resides in San Luis Obispo County, California. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a

proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, a life-threatening and debilitating lung condition. In or around October 2009, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary toxicity, a serious and potentially life-threatening lung condition. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In approximately April 2012, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Devi Pondicherry prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Pondicherry was a victim of the long-term and successful

promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Pondicherry did not receive FDA warnings from Defendant.

e) Dr. Pondicherry was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately June 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include trouble breathing, shortness of breath, wheezing, coughing, pulmonary hypertension, weakness, edema, nervousness, chronic pain, and fatigue. She was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary toxicity Plaintiff was a healthy and active individual. After developing pulmonary toxicity, she was often weak and struggled to walk across the room. She also had weight fluctuations and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary toxicity.

i) Additionally, Plaintiff Doug Hyak is the spouse of the Plaintiff Dianne Cruce, and resides with his spouse, and he depended on Dianne Cruce to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Dianne Cruce, Plaintiff Doug Hyak has in the past and will in the future suffer and incur loss of her consortium, loss of his spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

108. **Plaintiff Bill Worthington**

a) On personal knowledge, Bill Worthington, Personal Representative of the Estate of Bettye Worthington, deceased (hereinafter "Plaintiff" or "Worthington") is an individual who resides in Tulare County, California. Mrs. Worthington was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating pulmonary condition. In November 2011, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis and respiratory failure, serious and potentially deadly lung diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians

of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around November 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Attaran prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Attaran was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Attaran did not receive FDA warnings from Defendant.

e) Dr. Attaran was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately May 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, and chest pain. She was presented with a diagnosis of Amiodarone-induced pulmonary toxicity and pulmonary fibrosis. Pulmonary fibrosis is a

debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis and respiratory failure, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary fibrosis, she could not walk across the room, was often weak and short of breath. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis and respiratory failure.

i) After developing pulmonary fibrosis and respiratory fibrosis her condition deteriorated rapidly, requiring hospitalization. She could not adequately breathe on her own, requiring breathing assistance and oxygen use. After spending nearly two weeks in the hospital, Bettye Worthington succumbed to her Amiodarone-induced pulmonary fibrosis and respiratory failure on May 20, 2016.

109. **Plaintiff Birgitta Bengtsson**

a) On personal knowledge, Plaintiff Birgitta Bengtsson (hereinafter "Plaintiff" or "Bengtsson") is an individual who resides in Alameda County, California. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, thyroid damage and vision loss, all life-altering and debilitating conditions. In or around January 2017 she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed

Amiodarone-induced thyroid disease and vision loss, serious and potentially life-threatening conditions. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In approximately January 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Jamal Rana prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Jamal Rana was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Rana did not receive FDA warnings from Defendant.

e) Dr. Rana was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately April 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include vision loss, deposits in the eye, tremors, trouble breathing, coughing, weakness, edema, abnormal thyroid function, and fatigue. She was presented with a diagnosis of Amiodarone-induced pulmonary toxicity, thyroid damage, and vision loss. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary toxicity.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Prior to developing Amiodarone-induced pulmonary toxicity, thyroid damage and vision loss, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary toxicity, thyroid damage and vision loss, she can no longer exert herself and requires oxygen. She is often fatigued and short of breath, requiring hospitalization. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary toxicity and thyroid damage.

110. **Plaintiff Veronica Itano**

a) On personal knowledge, Plaintiff Veronica Itano, Personal Representative of the Estate of Phillip Itano, deceased, (hereinafter "Mrs. Itano") is an individual who resides in Orange County, California. Mr. Itano was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed

Amiodarone-induced acute pulmonary fibrosis, a life-threatening and debilitating condition. In February 2016, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around February 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Michael Radin prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Michael Radin was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of

Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Radin did not receive FDA warnings from Defendant.

e) Dr. Radin was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately February 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, loss of appetite, edema, and difficulty with exertion. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Mr. Itano was a healthy and active individual. After developing pulmonary fibrosis, he could not walk across the room and suffered frequent pneumonias. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) After developing pulmonary fibrosis, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring breathing assistance and oxygen use. After spending several days in the hospital, Phillip Itano succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on April 10, 2018.

111. **Plaintiff Diane Mancinelli**

a) On personal knowledge, Plaintiff Diane Mancinelli (hereinafter “Plaintiff” or “Mancinelli”) is an individual who resides in Nevada County, California. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease, a life-threatening and debilitating condition. In or around January 2014, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary disease, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around January 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA

warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Ryan Smith prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Ryan Smith was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Smith did not receive FDA warnings from Defendant.

e) Dr. Smith was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately January 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, chest pain, and difficulty walking. She was presented with a diagnosis of Amiodarone-induced pulmonary disease. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary lung disease is extremely poor. Pulmonary lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary disease, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary disease, she struggles with frequent pneumonias and is often weak and short of breath, requiring hospitalization at times. She also and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary disease.

112. **Plaintiff James Vinson, Jr.**

a) On personal knowledge, Plaintiff James Vinson, Jr. (hereinafter “Plaintiff” or “Vinson”) is an individual who resides in Autauga County, Alabama. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendant and as a proximate cause thereof, developed Amiodarone-induced interstitial lung disease, a life-threatening and debilitating condition. In or around April 2012, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced interstitial lung disease, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed

Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In April 2012, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Flemming prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Flemming was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Flemming did not receive FDA warnings from Defendant.

e) Dr. Flemming was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately December 2013, he began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, coughing, fatigue, weakness, and chest pain. He was presented with a diagnosis of Amiodarone-induced interstitial lung disease. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced interstitial lung disease is extremely poor. Amiodarone-induced interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced interstitial lung disease, Plaintiff was a healthy and very active individual. After developing Amiodarone-induced interstitial lung disease, he struggles to exert himself and requires full-time use of oxygen. He also suffers from a litany of other health problems related to his use of Amiodarone and other medications used to treat his Amiodarone-induced interstitial lung disease.

113. **Plaintiff Robert E. Smith**

a) On personal knowledge, Plaintiff Robert E. Smith (hereinafter "Plaintiff" or "Smith") is an individual who resides in Onondaga County, New York. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around November 2014, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor

receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In November 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Norman Jafe prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Norman Jafe was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Jafe did not receive FDA warnings from Defendant.

e) Dr. Jafe was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately August 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include trouble breathing, shortness of breath, wheezing, weakness, dizziness, chest pain, tremors and fatigue. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic,

progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, he was a healthy and very active individual. After developing pulmonary fibrosis, he struggles to exert himself and is often short of breath requiring oxygen. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

114. Plaintiff Amy Miller

a) On personal knowledge, Plaintiff Amy Miller, Personal Representative of the Estate of Larry Miller, deceased, (hereinafter "Plaintiff" or "Miller") is an individual who resides in Adams County, Pennsylvania. Mr. Miller was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary toxicity and respiratory failure, life-threatening and debilitating conditions. In October 2017, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a "rhythm medication," which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced acute pulmonary toxicity and respiratory failure, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe

and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around October 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Sumit Duggal prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Sumit Duggal was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Duggal did not receive FDA warnings from Defendant.

e) Dr. Duggal was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately November 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing,

trouble breathing, coughing, fatigue, weakness, trouble walking and respiratory failure. He was presented with a diagnosis of Amiodarone-induced acute pulmonary toxicity and respiratory failure. Amiodarone-induced acute pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced acute pulmonary toxicity, Mr. Miller was a healthy and active individual. After developing Amiodarone-induced pulmonary toxicity, he struggled to exert himself and was debilitated with weakness and shortness of breath, requiring oxygen. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced acute pulmonary toxicity.

i) After developing Amiodarone-induced acute pulmonary toxicity and respiratory failure, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring assistance. After spending several days in the hospital, Larry Miller succumbed to his Amiodarone-induced acute pulmonary toxicity and respiratory failure on December 26, 2017.

115. **Plaintiff Dorlis Lyle**

a) On personal knowledge, Plaintiff Doris Lyle, Personal Representative of the Estate of James Lyle, deceased (hereinafter "Lyle") is an individual who resides in Pettis County, Pennsylvania. Mr. Lyle was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone induced acute

pulmonary toxicity and respiratory failure, life-threatening and debilitating conditions. In June 2010, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced acute pulmonary toxicity and respiratory failure, serious and potentially deadly lung conditions. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In or around June 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Sedalia prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Sedalia was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial

fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Sedalia did not receive FDA warnings from Defendant.

e) Dr. Sedalia was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately September 2017, he began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, trouble walking and respiratory failure. He was presented with a diagnosis of Amiodarone-induced adult respiratory distress syndrome and pulmonary failure. Amiodarone-induced toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for the lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Prior to developing Amidoarone-induced lung disease and pulmonary failure. Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary toxicity, he struggled to exert himself and was debilitated with weakness and shortness of breath, requiring hospitalization. He also suffered from a litany of other health problems related to his use of Amidoarone and medications used to treat his Amiodarone-induced pulmonary toxicity.

i) After developing Amiodarone-induced pulmonary toxicity and respiratory failure, his condition deteriorated rapidly requiring hospitalization. He could not adequately breathe on his own, requiring oxygen assistance. After spending several days in the hospital, James Lyle succumbed to his Amiodarone-induced adult respiratory distress syndrome and respiratory failure on September 18, 2017.

116. **Plaintiffs David Wayne Gorbett and Norma Gorbett**

a) On personal knowledge, Plaintiff David Wayne Gorbett (hereinafter “Plaintiff” or “Gorbett”) is an individual who resides in Jackson County, Indiana. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around July 2017, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In July 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. David Hamilton prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. David Hamilton was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Hamilton did not receive FDA warnings from Defendant.

e) Dr. Hamilton was not aware that his use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and his prescription was for an "off-label" use.

f) Beginning in approximately June 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include trouble breathing, shortness of breath, coughing, wheezing, weakness, dizziness and fainting, chest pain and fatigue. He was presented with a diagnosis of pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale

of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, he was a remarkably healthy and active individual. After developing pulmonary fibrosis, he struggles to exert himself and can no longer live his active lifestyle he used to enjoy. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) Additionally, Plaintiff, Norma Gorbett is the spouse of the Plaintiff David Wayne Gorbett, and resides with her spouse, and she depended on David Wayne Gorbett to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff David Wayne Gorbett, Plaintiff Norma Gorbett has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

117. Plaintiffs Robert Ghiselin and Geri Ghiselin

a) On personal knowledge, Plaintiff Robert Ghiselin (hereinafter "Plaintiff" or "Ghiselin") is an individual who resides in Orange County, California. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss, a life-altering and debilitating condition. In or around June 2016, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced vision loss. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In June 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because they did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Patel and Dr. Thuy Le prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Patel and Dr. Thuy Le were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Patel and Dr. Le did not receive FDA warnings from Defendant.

e) Dr. Patel and Dr. Le were not aware that Plaintiff’s use of the medication was for an “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately March 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include vision loss, sudden blindness, optic nerve damage, poor coordination, dizziness, headaches and fatigue. He was presented with a diagnosis of Amiodarone-induced ischemic optic neuropathy resulting in vision loss. Amiodarone-induced ischemic optic neuropathy and vision loss is a debilitating, chronic, progressive condition that does not improve over time resulting in significant disability and impaired quality of life

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced ischemic optic neuropathy and vision loss, Plaintiff was a very healthy and active individual. After developing Amiodarone-induced vision complications, he can no longer see or independently perform daily life activities such as reading or driving. He also had to learn the Braille System and requires assistance in all activities. He also suffers from a litany of other health problems related to his use of Amiodarone.

i) Additionally, Plaintiff, Geri Ghiselin, is the spouse of the Robert Ghiselin, and resides with her spouse, and she depended on Robert Ghiselin to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Robert Ghiselin, Plaintiff Geri Ghiselin has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

118. **Plaintiffs George L. Bush and Edwin Martin**

a) Plaintiff George L. Bush (hereinafter "Plaintiff" or "Bush") is an individual who resides in Multnomah County, Oregon. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed

Amiodarone induced pulmonary toxicity, a life-threatening and debilitating condition. In December 2016, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary toxicity, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In December 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because they did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Blair and Dr. Halperin prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Blair and Dr. Halperin were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of

Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Blair and Dr. Halperin did not receive FDA warnings from Defendant.

e) Dr. Blair and Dr. Halperin were not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately May 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include trouble breathing, shortness of breath, coughing, sneezing, weakness, dizziness, chest pain, difficulty walking and fatigue. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive lung condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Prior to developing Amiodarone-induced pulmonary toxicity, Plaintiff was a healthy and very active individual. After developing Amiodarone-induced pulmonary toxicity, he struggles to exert himself and is often short of breath. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity.

i) Additionally, Plaintiff, Edwin Martin is the spouse of the Plaintiff George L. Bush, and resides with his spouse, and he depended on George L. Bush to be his primary caretaker as

they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff George L. Bush, Plaintiff Edwin Martin has in the past and will in the future suffer and incur loss of his consortium, loss of his spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for him.

119. **Plaintiff Brenda Barefoot**

a) On personal knowledge, Plaintiff Brenda Barefoot, Personal Representative of the Estate of Clark Barefoot, deceased, (hereinafter "Plaintiff" or "Barefoot") is an individual who resides in Johnson County, Kansas. Mr. Barefoot was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis and respiratory failure, life-threatening and debilitating conditions. In January 2011, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a "rhythm medication," which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis and respiratory failure, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed

Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around August 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. George Pierson prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. George Pierson was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Pierson did not receive FDA warnings from Defendant.

e) Dr. Pierson was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately July 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, weight loss, confusion, abdominal pain, and respiratory failure. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis and respiratory failure. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary fibrosis and respiratory failure, Mr. Barefoot was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary fibrosis and respiratory failure, he struggled to exert himself and developed pneumonia and shortness of breath, requiring hospitalization. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) After developing Amiodarone-induced pulmonary fibrosis, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring life support and ventilation assistance. After spending several days in the hospital, Clark Barefoot succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on January 24, 2018.

120. **Plaintiff Mary Parker**

a) On personal knowledge, Plaintiff Mary Parker (hereinafter "Plaintiff" or "Parker") is an individual who resides in Rutherford County, Indiana. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In April 2011, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-

threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around April 2011, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Aravind Reddy prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Aravind Reddy was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Reddy did not receive FDA warnings from Defendant.

e) Dr. Reddy was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial

fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately April 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, edema, coughing, fatigue, and weakness. She was presented with a diagnosis of pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis, she struggled to walk or exert herself. She became dependent on oxygen to breathe adequately. Due to her Amiodarone-induced pulmonary fibrosis, she became more susceptible to developing frequent pneumonias resulting in frequent hospitalizations and treatment. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis including cardiomegaly, and pulmonary hypertension.

i) In or about June 2016, Plaintiff discovered a Facebook page, discussing the serious complications of Amiodarone, including pulmonary fibrosis, and the fact it was not FDA-approved for treatment of atrial fibrillation. Immediately thereafter, she sought legal representation regarding her injuries. The Facebook page in question was not published until 2015. It was not until she learned of these facts that she knew, or reasonably should have known, that the injuries she suffered were caused by wrongdoing on the part of the Defendants.

121. **Plaintiffs Don Ash and Janna Ash**

a) On personal knowledge, Plaintiff Don Ash (hereinafter “Plaintiff” or “Ash”) is an individual who resides in Floyd County, Georgia. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendant and as a proximate cause thereof, developed Amiodarone-induced interstitial lung disease and pulmonary toxicity, both life-threatening and debilitating conditions. In or around March 2018, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced interstitial lung disease and pulmonary toxicity. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In April 2018, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Robert Styperek prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial

fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Robert Styperek was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Styperek did not receive FDA warnings from Defendant.

e) Dr. Styperek was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately October 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, coughing, weakness, chest pain, edema, confusion, weight gain and fatigue. He was presented with a diagnosis of Amiodarone-induced interstitial lung disease and pulmonary toxicity. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The survival rate for individuals with Amiodarone-induced interstitial lung disease is extremely poor. Amiodarone-induced interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced interstitial lung disease and pulmonary toxicity, Plaintiff was a healthy and very active individual. After developing Amiodarone-induced

interstitial lung disease, he struggles to exert himself and can no longer enjoy his once active lifestyle. In addition, he has suffered from severe pneumonia requiring hospitalization as well as new onset of type II diabetes, which his physician believes arrived as a side effect of his required steroids used to manage his pulmonary disease. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced injuries.

i) Additionally, Plaintiff Janna Ash is the spouse of the Plaintiff Don Ash, and resides with her spouse, and she depended on Don Ash to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Don Ash, Plaintiff Janna Ash has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

122. **Plaintiff Imogene Berry**

a) On personal information, Plaintiff Imogene Berry (hereinafter "Plaintiff" or "Berry") is an individual who resides in Collin County, Texas. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Zydus and potentially other manufacturers and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, respiratory failure, thyroid disease, and vision loss, all life-threatening and debilitating conditions. In or around July 2015, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary toxicity, respiratory failure, thyroid disease, and vision loss. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around July 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Manish Assar prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Manish Assar was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Assar did not receive FDA warnings from Defendant.

e) Dr. Assar was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, she was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its

bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in or around March 2019, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include difficulty breathing and shortness of breath, exhaustion, dizziness, weight loss, confusion, thyroid disease, vision loss and fatigue. She was presented with a diagnosis of Amiodarone-induced pulmonary toxicity and respiratory failure. Amiodarone-induced pulmonary toxicity and respiratory failure are debilitating chronic, progressive lung conditions that only worsen over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity and respiratory failure is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary toxicity, respiratory failure, thyroid disease and vision loss, Plaintiff was a healthy and active individual. After developing Amiodarone-induced pulmonary toxicity, respiratory failure, thyroid disease, and vision loss, she struggles to exert herself and can no longer independently perform daily life activities. In addition, she has suffered from recurrent pneumonias and severe difficulty breathing requiring frequent hospitalizations. Her breathing has become increasingly labored, requiring the use of a BiPap machine and oxygen supplementation. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced complications.

123. **Plaintiff Francis Dodd**

a) On personal knowledge, Plaintiff Francis Dodd (hereinafter “Plaintiff” or “Dodd”) is an individual who resides in Piatt County, Illinois. He was prescribed, purchased, and ingested

the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity and respiratory failure, which are life-threatening and debilitating conditions. In or around November 2018, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary toxicity and respiratory failure, both serious and potentially deadly complications. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around November 2018, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Reddy prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug

Amiodarone as prescribed. Dr. Reddy was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Reddy did not receive FDA warnings from Defendant.

e) Dr. Reddy was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately April 2019, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, weakness, difficulty walking, kidney damage and fatigue. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity and respiratory failure. Amiodarone-induced pulmonary toxicity and respiratory failure are debilitating, chronic, progressive conditions that only worsen over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after his diagnosis that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing Amiodarone-induced pulmonary toxicity and respiratory failure, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary toxicity and respiratory failure, he struggles to exert himself and requires oxygen, and suffers from frequent pneumonia. In addition, he has suffered from kidney disease and severe

muscle weakness making him unable to walk on his own. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity.

124. **Plaintiff Theresa Graves**

a) On personal knowledge, Plaintiff Theresa Graves, Personal Representative of the Estate of Robert Graves, deceased, (hereinafter “Plaintiff” or “Graves”) is an individual who resides in Marion County, Oregon. Mr. Graves was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced interstitial lung disease, pulmonary toxicity, and kidney disease, all life-threatening and debilitating conditions. In May 2014, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced interstitial lung disease, pulmonary toxicity, and kidney disease, all serious and potentially deadly conditions. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around September 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because they did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Patel and Dr. Ganhok prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Patel and Dr. Ganhok were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Patel and Dr. Ganhok did not receive FDA warnings from Defendant.

e) Dr. Patel and Dr. Ganhok were not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately August 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, weight gain, kidney damage and fatigue. He was presented with a diagnosis of Amiodarone-induced interstitial lung disease and pulmonary toxicity. Intersitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Intersitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she

became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced interstitial lung disease, Mr. Graves was a healthy and active individual. After developing Amiodarone-induced pulmonary and kidney disease, he struggled to exert himself and his health rapidly declined. In addition, his difficulty breathing worsened requiring hospitalization and intensive medical treatment. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced interstitial lung disease.

i) After developing Amiodarone-induced interstitial lung disease, pulmonary toxicity and kidney disease, his condition continued to worsen. He could not adequately breathe on his own, requiring medical support. After several hospitalizations, Robert Graves succumbed to his Amiodarone-induced interstitial lung disease, kidney disease and respiratory failure on November 27, 2019.

125. **Plaintiffs Ann Morisey and Charles Morisey**

a) On personal knowledge, Plaintiff Ann Morisey (hereinafter "Plaintiff" or "Morisey") is an individual who resides in Comal County, Texas. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced interstitial lung disease and respiratory failure, life-threatening and debilitating conditions. In or around March 2018, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced interstitial lung disease and respiratory failure, serious and potentially deadly lung diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In March 2018 as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Robert Schnitzler prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Robert Schnitzler was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Schnitzler did not receive FDA warnings from Defendant.

e) Dr. Schnitzler was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of

Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately June 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, decreased appetite, nausea, weakness, abnormal liver disease and fatigue. She was presented with a diagnosis of Amiodarone-induced interstitial lung disease and respiratory failure. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced interstitial lung disease and respiratory failure, she was a remarkably healthy and active individual. After developing Amiodarone-induced interstitial lung disease and respiratory failure, she struggles to exert herself and can no longer independently perform daily life activities. In addition, she has suffered from recurrent pneumonias and severe difficulty breathing, requiring hospitalizations. Her condition declined rapidly during her hospitalization, requiring intensive care, intubations, and oxygen supplementation. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced interstitial lung disease and respiratory failure.

i) Additionally, Plaintiff Charles Morisey is the spouse of the Plaintiff Ann Morisey and resides with his spouse, and he depended on Ann Morisey to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Ann Morisey, Plaintiff Charles Morisey, has in the past and will in the future suffer and incur loss

of her consortium, loss of his spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

126. **Plaintiff Harsharan Sandhu**

a) On personal knowledge, Harsharan Sandhu, Personal Representative of the Estate of Gurdip Sandhu, deceased (hereinafter "Plaintiff" or "Sandhu") is an individual who resides in Fresno County, California. Ms. Sandhu was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity and respiratory failure, life-threatening and debilitating conditions. In or around 2013, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary toxicity and respiratory failure, serious and potentially deadly lung diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for "off-label" use by them.

d) In or around June 2018, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Jagroop Basraon prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Jagroop Basraon was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Basraon did not receive FDA warnings from Defendant.

e) Dr. Basraon was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an "off-label" use.

f) Beginning in approximately May 2019, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, edema, and severe weakness. She was presented with a diagnosis of Amiodarone-induced pulmonary toxicity and respiratory failure. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she

became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary toxicity and respiratory failure, Plaintiff was a healthy and active individual. After developing pulmonary toxicity and respiratory failure, she struggled to breathe and developed pneumonia. Her difficulty breathing worsened requiring hospitalization. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis and respiratory failure.

i) After developing Amiodarone-induced pulmonary toxicity and respiratory fibrosis her condition continued to worsen. She could not adequately breathe on her own, requiring surgical intervention and intubation. After several days in the hospital, Gurdip Sandhu succumbed to her Amiodarone-induced pulmonary toxicity and respiratory failure on August 1, 2019.

127. **Plaintiffs John Hendrix and Linda Perry**

a) Plaintiff, John Hendrix (hereinafter "Plaintiff" or "Hendrix") is an individual who resides in East Baton Rouge County, Louisiana. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around 2010, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe

and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Kevin Kilpatrick prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Kilpatrick was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Kilpatrick did not receive FDA warnings from Defendant.

e) Dr. Kilpatrick was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) In approximately February 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, chest pain, weakness, and dizziness. He was presented with a

diagnosis of Amiodarone-induced pulmonary fibrosis. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing pulmonary fibrosis, he was a remarkably healthy and active individual. After developing pulmonary fibrosis, he struggles to exert himself and requires oxygen. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) Additionally, Plaintiff, Linda Perry is the spouse of the Plaintiff John Hendrix, and resides with her spouse, and she depended on Plaintiff, John Hendrix to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff, John Hendrix, Plaintiff, Linda Perry has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

128. Plaintiffs James Jordan and Sharon Jordan

a) On personal knowledge, Plaintiff James Jordan (hereinafter "Plaintiff" or "Jordan") is an individual who resides in Smith County, Mississippi. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, thyroid disease, and kidney injuries, all life-threatening and debilitating conditions. In or around August 2009, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of

the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, thyroid disease, and kidney injuries, all serious and potentially deadly complications. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around August 2009, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Lawrence Leader prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Lawrence Leader was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to

prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Leader did not receive FDA warnings from Defendant.

e) Dr. Leader was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately February 2011, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, coughing, wheezing, trouble breathing, fatigue, chest pain, memory loss, abnormal thyroid, kidney and liver functions, weakness and headaches. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis, thyroid disease, and kidney injuries. Amiodarone-induced pulmonary fibrosis is a debilitating, chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after his diagnosis that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing Amiodarone-induced pulmonary fibrosis, thyroid disease, and kidney injuries, he was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary fibrosis, thyroid disease, and kidney injuries, he struggles to exert himself and is often fatigued and short of breath. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) Additionally, Plaintiff, Sharon Jordan is the spouse of the Plaintiff James Jordan, and resides with her spouse, and she depended on James Jordan to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff James Jordan, Plaintiff Sharon Jordan has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

129. **Plaintiff Charles Price**

a) On personal information, Plaintiff, Charles Price (hereinafter "Plaintiff" or "Price") is an individual who resides in Riverside County, California. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease, a life-threatening and debilitating condition. In November 2013, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary disease, a serious and potentially deadly lung condition. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed

Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In November 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Bernstein prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Bernstein was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Bernstein did not receive FDA warnings from Defendant.

e) Dr. Bernstein was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) In approximately 2014, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, fatigue, coughing, chest pain, abnormal heart rate, bruising, dizziness and weakness. He was presented with a diagnosis of Amiodarone-induced pulmonary disease. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing Amiodarone-induced pulmonary disease, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary disease, he could not easily exert himself and was often fatigued and short of breath. He also suffers from a litany of other health problems apparently related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary disease.

130. **Plaintiffs James Roadcap, Sr. and Edna Roadcap**

a) On personal information, Plaintiff, James Roadcap, Sr. (hereinafter "Plaintiff" or "Roadcap") is an individual who resides in Rockingham County, Virginia. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In September 2003, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a "rhythm medication" by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor

receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In approximately September 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Bryan Sauer prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Bryan Sauer was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Sauer did not receive FDA warnings from Defendant.

e) Dr. Sauer was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately May 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, fatigue, chest pain, weakness and dizziness. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate

for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. The survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing Amiodarone-induced pulmonary fibrosis, he was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary fibrosis, he struggles to exert himself and is often short of breath. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) Additionally, Plaintiff, Edna Roadcap is the spouse of the Plaintiff James Roadcap, and resides with her spouse, and she depended on Plaintiff, James Roadcap to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff, James Roadcap, Plaintiff, Edna Roadcap has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

131. **Plaintiff Patricia Sopp**

a) Plaintiff Patricia Sopp, as Administrator of the Estate of Philip C. Sopp, deceased, (hereinafter "Plaintiff" or "Sopp") is an individual who resides in Allegheny County, Pennsylvania. Her deceased husband, Philip, was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone induced pulmonary fibrosis, a life-threatening and debilitating condition. In February

2015, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In February 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Ryan Zuzek prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Ryan Zuzek was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to

Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Zuzek did not receive FDA warnings from Defendant.

e) Dr. Zuzek was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately April 2015, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, nervousness, irritability, restlessness, decreased concentration, and depression. He was presented with a diagnosis of pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, he was a remarkably healthy and active individual. After developing pulmonary fibrosis, he could not walk across the room. He also lost weight and suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis. Philip Sopp succumbed to his Amiodarone-induced pulmonary fibrosis on May 6, 2015.

132. **Plaintiff Barbara Clark**

a) On personal knowledge, Barbara Clark, Personal Representative of the Estate of Roy L. Clark, deceased (hereinafter "Plaintiff" or "Clark") is an individual who resides in Franklin

County, Kentucky. Mr. Clark was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In 2009, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around 2009, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Keedy prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as

prescribed. Dr. Keedy was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Keedy did not receive FDA warnings from Defendant.

e) Dr. Keedy was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately April 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, tiredness, weakness, restlessness, decreased concentration, depression, and respiratory failure. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Plaintiff was healthy and active individual. After developing pulmonary fibrosis, he could not exert himself and experienced difficulty breathing. He enjoyed spending quality time with his family and was able to perform daily activities. After developing these complications, his condition deteriorated rapidly. He could not

catch his breath and suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced complications. As his condition continued to worsen, Roy Clark succumbed to his Amiodarone-induced pulmonary fibrosis on June 11, 2016.

133. **Plaintiff Krikor Pechakjian**

a) On personal information, Plaintiff, Krikor Pechakjian (hereinafter “Plaintiff” or “Pechakjian”) is an individual who resides in Los Angeles County, California. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around 1989, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In or around 1989, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Eric T. Lee prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Eric T. Lee was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Lee did not receive FDA warnings from Defendant.

e) Dr. Lee was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) In approximately 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, fatigue, coughing, weakness, vision loss, edema, decreased neurological function and muscular issues. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. The survival rate for individuals with Amiodarone-induced pulmonary fibrosis is extremely poor. Amiodarone-induced pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he

became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants

h) Before developing Amiodarone-induced pulmonary fibrosis, he was a remarkably healthy and active individual. After developing pulmonary fibrosis, he could not walk across the room and required full-time use of oxygen. He also suffers from a litany of other health problems apparently related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary disease.

134. **Plaintiff Debra Lister**

a) On personal knowledge, Plaintiff Debra Lister, Personal Representative of the Estate of Mark Anthony, deceased, (hereinafter "Plaintiff" or "Anthony") is an individual who resides in Clark County, Nevada. Mr. Anthony was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In January 2008, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a "rhythm medication," which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around January 2010, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Wagner prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Wagner was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Wagner did not receive FDA warnings from Defendant.

e) Dr. Wagner was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately December 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include coughing, wheezing, shortness of breath, dizziness, fatigue, difficulty walking and chest pain. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary

fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary fibrosis, Mr. Anthony was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary fibrosis, he struggled to exert himself, and had limited mobility. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) After developing Amiodarone-induced pulmonary fibrosis, his condition deteriorated rapidly. He could not adequately breathe on his own and his condition worsened. Mark Anthony succumbed to his Amiodarone-induced pulmonary fibrosis on May 11, 2018.

135. **Plaintiff Raymond Wright**

a) On personal knowledge, Plaintiff Raymond Wright, Personal Representative of the Estate of Sarianne Wright, deceased, (hereinafter "Plaintiff" or "Wright") is an individual who resides in Kanawha County, West Virginia. Mrs. Wright was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, a life-threatening and debilitating condition. In or around November 2014, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. Her cardiologist prescribed her a "rhythm medication," which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about potential life-

threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around November 2014, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because they did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Gallagher and Dr. Babar prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Gallagher and Dr. Babar were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Gallagher and Dr. Babar did not receive FDA warnings from Defendant.

e) Dr. Gallagher and Dr. Babar were not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last

resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately May 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, difficulty breathing, coughing, fatigue, tremors, dizziness, vision loss, weakness and thyroid damage. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis disease is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary fibrosis, Mrs. Wright was a healthy and active individual. After developing Amiodarone-induced pulmonary fibrosis she could not walk across the room and struggled to exert herself. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis.

i) After developing Amiodarone-induced pulmonary fibrosis, her condition deteriorated rapidly. She could not breathe adequately and required breathing assistance and oxygen use. After several different hospital admissions, Sarianne Wright succumbed to her Amiodarone-induced pulmonary fibrosis on March 17, 2017.

136. **Plaintiff Jaclyn Carter**

a) On personal knowledge, Jaclyn Carter, Personal Representative of the Estate of Jack Carter, deceased (hereinafter “Plaintiff” or “Carter”) is an individual who resides in Jones

County, Mississippi. Mr. Carter was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary toxicity and respiratory failure, a life-threatening and debilitating lung condition. In or around July 2017, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary toxicity and respiratory failure, both serious and potentially deadly lung diseases. He received no warning from his physician about these potential life-threatening complications, nor did any warnings accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In July 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because they did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Robert Long and Dr. Douglas Wolfe prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug

Amiodarone as prescribed. Dr. Robert Long and Dr. Douglas Wolfe were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Long and Dr. Wolfe did not receive FDA warnings from Defendant.

e) Dr. Long and Dr. Wolfe were not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately August 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, edema, severe weakness, anxiety and respiratory failure. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity and respiratory failure. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Prior to developing Amiodarone-induced pulmonary toxicity and pulmonary failure, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary toxicity, he struggled to exert himself and developed severe shortness of breath, requiring hospitalization. He also suffered from a litany of other health problems related

to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity.

i) After developing Amiodarone-induced pulmonary toxicity and respiratory failure his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring BiPap and then ventilation assistance. After spending several days in the hospital, Jack Carter succumbed to his Amiodarone-induced pulmonary toxicity and respiratory failure on September 26, 2018.

137. **Plaintiff Marsha McCrory**

a) On personal knowledge, Plaintiff Marsha McCrory (hereinafter "Plaintiff" or "McCrory") is an individual who resides in Cook County, Illinois. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced interstitial lung disease, pulmonary toxicity and respiratory failure, life-altering and debilitating lung conditions. In or around February 2017, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced interstitial lung disease, pulmonary toxicity and respiratory failure, all potentially life-threatening pulmonary diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around March 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Sulman Hussain prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Sulman Hussain was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Hussain did not receive FDA warnings from Defendant.

e) Dr. Hussain was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately May 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include trouble breathing, shortness of breath, coughing, wheezing, weakness, kidney and fatigue. She was presented with a diagnosis of Amiodarone-induced interstitial lung disease and respiratory failure. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive lung condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced interstitial lung disease

is extremely poor. Amiodarone-induced interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Prior to developing Amiodarone-induced interstitial lung disease and respiratory failure, Plaintiff was a healthy and active individual. After developing Amiodarone-induced pulmonary disease and respiratory failure, she struggles to exert herself and requires oxygen to breathe adequately. As a result of these injuries she suffers from frequent pneumonias resulting in multiple long-term hospitalizations. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced interstitial lung disease.

138. **Plaintiff Carla Ellis**

a) On personal knowledge, Carla Ellis, Personal Representatives of the Estate of Iva Walker, deceased (hereinafter "Plaintiff" or "Walker") is an individual who resides in Jefferson County, Illinois. Ms. Walker was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity and respiratory failure, a life-threatening and/or debilitating condition. In or around October 2016, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary toxicity and respiratory failure, serious and potentially deadly lung diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around November 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because they did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Fadi and Dr. Apostol prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Fadi and Dr. Apostol were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Fadi and Dr. Apostol did not receive FDA warnings from Defendant.

e) Dr. Fadi and Dr. Apostol were not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of

Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately March 2019, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include chest pain, shortness of breath, weakness, coughing, pneumonia, and fatigue. She was presented with a diagnosis of Amiodarone-induced pulmonary toxicity and respiratory failure. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive conditions that may worsen over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants’ role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Prior to developing Amiodarone-induced lung toxicity and respiratory failure, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced pulmonary injuries, she could no longer adequately breathe on her own and developed frequent pneumonia. As a result of developing pulmonary toxicity and secondary pneumonia she was often fatigued and short of breath and in need of urgent medical care. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced lung disease including kidney damage and congestive heart failure.

i) After developing Amiodarone-induced pulmonary toxicity and respiratory failure her condition deteriorated rapidly requiring hospitalization. She could not adequately perform daily life activities on her own and became dependent on medical care requiring oxygen and BiPAP assistance for breathing. After spending several days in the hospital, Iva Walker succumbed to her Amiodarone-induced pulmonary toxicity and respiratory failure on May 31, 2019.

139. **Plaintiff Nancy Barber**

a) On personal knowledge, Nancy Barber, Personal Representative of the Estate of John Glynne Barber, deceased (hereinafter “Plaintiff” or “Barber”) is an individual who resides in Wilson County, North Carolina. Mr. Barber was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary fibrosis, a life-threatening and debilitating condition. In or around January 2017, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis and pulmonary toxicity, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In January 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. David Frazier

prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. David Frazier was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Frazier did not receive FDA warnings from Defendant.

e) Dr. Frazier was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately February 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, fatigue and weakness. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Plaintiff was a remarkably healthy and active individual. After developing pulmonary fibrosis, he struggled to exert himself and could no

longer cut the grass or perform property maintenance and repairs. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) After developing Amiodarone-induced pulmonary fibrosis and pulmonary toxicity his condition deteriorated rapidly, requiring hospitalization. After spending several days in the hospital, John Glynne Barber succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on May 24, 2018.

140. **Plaintiff Rita Pennington**

a) On personal knowledge, Plaintiff Rita Pennington (hereinafter “Plaintiff” or “Pennington”) is an individual who resides in Pinellas County, Florida. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and acute pulmonary fibrosis, a life-threatening and debilitating lung condition. In January 2015 she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a “rhythm medication” by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted sold for “off-label” use by them.

d) In January 2015, as a result of the long term and pervasive promotional activities of brand innovator Wyeth and other Defendants to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Paul Phillips prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Paul Phillips was a victim of the long term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Phillips did not receive FDA warnings from Defendant.

e) Dr. Phillips was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and her prescription was for an “off-label” use.

f) Beginning in approximately April 2018, Plaintiff began to experience shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, and difficulty with exertion. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary, Plaintiff was a remarkably healthy and active individual. After developing these injuries, she could not easily exert herself, was often fatigued and short of breath. She also and suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis.

141. Plaintiffs Roberta Schroeder and Carl Schroeder

a) On personal knowledge, Plaintiff Roberta Schroeder (hereinafter "Plaintiff" or "Schroeder") is an individual who resides in Sheboygan County, Wisconsin. She was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary toxicity, respiratory failure, thyroid damage and vision loss, all life-altering and debilitating conditions. In or around March 2011, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary toxicity, respiratory failure, thyroid damage and vision loss, all potentially life-threatening diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her

doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d) In or around March 2011, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because they did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Bahtia and Dr. Khan prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Bahtia and Dr. Khan were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Bahtia and Dr. Khan did not receive FDA warnings from Defendant.

e) Dr. Bahtia and Dr. Khan were not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately June 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include trouble breathing, shortness of breath, coughing, weakness, weight loss, vision loss, kidney failure and fatigue. She was presented with a

diagnosis of Amiodarone-induced pulmonary toxicity, respiratory failure, vision loss and thyroid damage. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive lung condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Prior to developing Amiodarone-induced pulmonary toxicity, vision loss respiratory failure, and thyroid disease Plaintiff was a healthy and active individual. After developing Amiodarone-induced pulmonary disease and respiratory failure, she struggles to exert herself and requires oxygen to breathe adequately. As a result of these injuries she suffers from frequent pneumonias resulting in multiple long-term hospitalizations. She also suffers from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced lung disease including vision loss, and thyroid damage.

i) Additionally, Plaintiff Carl Schroeder is the spouse of the Plaintiff Roberta Schroeder, and resides with his spouse, and he depended on Roberta Schroeder to be his primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Roberta Schroeder, Plaintiff Carl Schroeder, has in the past and will in the future suffer and incur loss of her consortium, loss of his spouse's services, the cost and expense of having medical care, the cost of travel necessary to secure said medical care, attention and treatment for his spouse and the cost of related medical expense for her.

142. **Plaintiff Lloyce Parr**

a) On personal knowledge, Plaintiff Lloyce Parr, Personal Representative of the Estate of Delmas Parr, deceased, (hereinafter "Plaintiff" or "Parr") is an individual who resides in

Jefferson County, Alabama. Mr. Parr was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis and respiratory failure, life-threatening and debilitating conditions. In July 2016, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis and respiratory failure, serious and potentially deadly lung conditions. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around August 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Rashid Ashraf prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and

ingested the drug Amiodarone as prescribed. Dr. Rashid Ashraf was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Ashraf did not receive FDA warnings from Defendant.

e) Dr. Ashraf was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately March 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, abnormal thyroid and kidney function, and respiratory failure. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis and respiratory failure. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Mr. Parr was a healthy and active individual. After developing pulmonary fibrosis, he could no longer live an active lifestyle and was soon hospitalized. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

j) After developing Amiodarone-induced pulmonary fibrosis and respiratory failure, his condition deteriorated rapidly requiring hospitalization. He could not adequately breathe on his own requiring oxygen, ventilation and intensive care. After spending several days in the hospital, Delmas Parr succumbed to his Amiodarone-induced pulmonary fibrosis and respiratory failure on April 29, 2018.

143. Plaintiff Patricia Rhodes

a) On personal knowledge, Patricia Rhodes, Personal Representative of the Estate of Rex Rhodes, deceased (hereinafter “Plaintiff” or “Rhodes”) is an individual who resides in Gillespie County, Mississippi. Mr. Rhodes was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary toxicity and respiratory failure both debilitating and life-threatening lung conditions. In or around August 2010, he was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary toxicity and respiratory failure both potentially deadly diseases. He received no warning from his physician about these potential life-threatening complications, nor did any warnings accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed

Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In February 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Kevin Gallagher prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Kevin Gallagher was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Gallagher did not receive FDA warnings from Defendant.

e) Dr. Gallagher was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately August 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, trouble breathing, coughing, fatigue, weakness, poor coordination, abnormal heart rate and respiratory failure. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity and respiratory failure. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary toxicity is extremely poor. Amiodarone-induced pulmonary toxicity causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Prior to developing Amiodarone-induced pulmonary toxicity and respiratory failure, Plaintiff was a remarkably healthy and active individual. After developing these Amiodarone-induced injuries, he could no longer live an active lifestyle and was soon hospitalized. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity including congestive heart failure and sepsis.

i) After developing Amiodarone-induced pulmonary toxicity and respiratory failure his condition deteriorated rapidly requiring hospitalization. He could not adequately breathe on his own, requiring oxygen and ventilation. After spending nearly a month in the hospital, Rex Rhodes succumbed to his Amiodarone-induced pulmonary toxicity and respiratory failure on October 9, 2018.

144. **Plaintiff James Thomas**

a) On personal knowledge, Plaintiff James Thomas, Personal Representative of the Estate of Syble Thomas, deceased, (hereinafter "Plaintiff" or "Thomas") is an individual who resides in Ouachita Parish, Louisiana. Mrs. Thomas was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary fibrosis, puolmonary toxicity, and respiratory failure, life-threatening and debilitating conditions. In or around April 2017, she was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. Her cardiologist prescribed her a "rhythm medication," which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. She received no warning from

her physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around April 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Craig Turner prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Craig Turner was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected her decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Turner did not receive FDA warnings from Defendant.

e) Dr. Turner was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately March 2019, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include trouble breathing, shortness of breath, coughing, wheezing, severe weakness and fatigue. She was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis, pulmonary toxicity, and respiratory failure. Amiodarone-induced pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary fibrosis disease is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary fibrosis, pulmonary toxicity, and respiratory failure, Mrs. Thomas was a healthy and active individual. After developing Amiodarone-induced pulmonary fibrosis, pulmonary toxicity and respiratory failure, she struggled to breathe and was often lethargic. Her difficulty breathing worsened requiring hospitalization. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary fibrosis.

i) After developing Amiodarone-induced pulmonary fibrosis, pulmonary toxicity and respiratory failure, her condition continued to worsen. She could not adequately breathe on her own, requiring medical intervention. After several days in the hospital, Syble Thomas succumbed

to her Amiodarone-induced pulmonary fibrosis, pulmonary toxicity and respiratory failure on April 6, 2019.

145. **Plaintiff Diana Cutright**

a) On personal knowledge, Plaintiff Diana Cutright, Personal Representative of the Estate of Richard Cutright, deceased, (hereinafter “Plaintiff” or “Cutright”) is an individual who resides in Columbia County, Georgia. Mr. Cutright was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute interstitial lung disease and respiratory failure, a life-threatening and debilitating condition. In February 2019, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced interstitial lung disease, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around February 2019, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below,

along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Stephen Broadwater prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Stephen Broadwater was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Broadwater did not receive FDA warnings from Defendant.

e) Dr. Broadwater was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately March 2019, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, chest pain, edema and respiratory failure. He was presented with a diagnosis of Amiodarone-induced respiratory failure and interstitial lung disease. Amiodarone-induced interstitial lung disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Amiodarone-induced interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale

of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary injuries, disease, Mr. Cutright was a healthy and active individual. After developing Amiodarone-induced interstitial lung disease and respiratory failure, he could not exert himself or adequately breathe on his own. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced interstitial lung disease.

i) After developing Amiodarone-induced interstitial lung disease and respiratory failure, his condition deteriorated rapidly, requiring intensive care hospitalization. He could not adequately breathe on his own, requiring assistance. After spending several weeks in the hospital, Richard Cutright succumbed to his Amiodarone-induced interstitial lung disease and respiratory failure on April 28, 2019.

146. Plaintiffs Jerry Coss and Brenda Coss

a. On personal knowledge, Plaintiff, Jerry Coss (hereinafter “Plaintiff” or “Coss”) is an individual who resides in Tuscaloosa County, Alabama. He was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced idiopathic neuropathy, a life-altering and debilitating condition. In or around May 2015, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced idiopathic neuropathy. He received no warning from his physician about the potential life-altering complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b. At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative

to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c. Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and/or promoted and sold for “off-label” use by them.

d. In or around May 2015, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Jeffrey Anderson prescribed him a course of 200 mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Jeffrey Anderson was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Anderson did not receive FDA warnings from Defendant.

e. Dr. Anderson was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f. Beginning in approximately 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include edema, fatigue, sudden and severe weakness, inability to walk, severe neuropathy, numbness, tingling, and other neurological side

effects. He was presented with a diagnosis of Amiodarone-induced idiopathic neuropathy. Amiodarone-induced idiopathic neuropathy is a debilitating, chronic progressive neurological condition that may worsen over time. Amiodarone-induced idiopathic neuropathy greatly impacts the neurological system causing debilitating side effects such as weakness, poor coordination, loss of muscle function, and inability to walk.

g. He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after this diagnosis that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h. Before developing Amiodarone-induced idiopathic neuropathy, Plaintiff was a remarkably healthy and active individual. After developing Amiodarone-induced idiopathic neuropathy, he struggles with severe weakness and can no longer walk independently, requiring this use of a wheelchair. In addition, he has had to undergo multiple medical procedures and tests due to his symptoms and requires full-time care. He also suffers from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced idiopathic neuropathy.

i. Additionally, Plaintiff Brenda Coss is the spouse of the Plaintiff Jerry Coss and resides with her spouse, and she depended on Plaintiff Jerry Coss to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff Jerry Coss, Plaintiff Brenda Coss has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for him, the cost of travel necessary to secure said medical care, attention and treatment for her spouse and the cost of related medical expense for him.

147. **Plaintiff Andrea Miller**

a) On personal knowledge, Plaintiff Andrea Miller, Personal Representative of the Estate of Charles Miller, deceased (hereinafter "Plaintiff" or "Miller") is an individual who resides in Lake County, Indiana. Mr. Miller was prescribed, purchased, and ingested the drug commonly

referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary fibrosis, thyroid disease, and respiratory failure, all life-threatening and debilitating conditions. In April 2016, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, thyroid disease, and respiratory failure, all serious and potentially deadly conditions. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around April 2016, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Joseph Stella prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and

ingested the drug Amiodarone as prescribed. Dr. Joseph Stella was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Stella did not receive FDA warnings from Defendant.

e) Dr. Stella was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately September 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include trouble breathing, shortness of breath, coughing, severe weakness, muscle pain, excessive bleeding, abnormal thyroid function and fatigue. He was presented with a diagnosis of Amiodarone-induced pulmonary fibrosis. Thyroid disease, and respiratory failure. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, thyroid disease and respiratory failure, Mr. Miller was a healthy and active individual. After developing pulmonary fibrosis, thyroid disease and respiratory failure, he struggled to breathe and was often lethargic. He also suffered from a

litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) After developing pulmonary fibrosis, thyroid disease and respiratory failure, his condition continued to worsen. He could not adequately breathe on his own, requiring medical intervention and oxygen. After spending several days in the hospital, Charles Simmons succumbed to his Amiodarone-induced pulmonary fibrosis, thyroid disease and respiratory failure on May 24, 2018.

148. **Plaintiff Diane Desmond**

a) On personal knowledge, Plaintiff Diane Desmond, Personal Representative of the Estate of Philip Schub, deceased (hereinafter “Plaintiff” or “Schub”) is an individual who resides in Maricopa County, Arizona. Mr. Schub was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary toxicity and respiratory failure, life-threatening and debilitating conditions. In or around October 2017, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced pulmonary fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around October 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Luis Scott prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Luis Scott was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Scott did not receive FDA warnings from Defendant.

e) Dr. Scott was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately August 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, edema, weight gain, weakness and respiratory failure. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity and respiratory failure. Amiodarone-induced pulmonary toxicity is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced

pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Mr. Schub was a remarkably healthy and active individual. After developing Amiodarone-induce pulmonary toxicity, he struggled to exert himself and developed severe shortness of breath, requiring hospitalization. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary toxicity.

i) After developing Amiodarone-induced pulmonary toxicity and respiratory failure, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring intensive care and oxygen support. After spending several days in the hospital, Philip Schub succumbed to his Amiodarone-induced pulmonary toxicity and respiratory failure on January 17, 2019.

149. Plaintiff Bruce Wehling

a) On personal knowledge, Plaintiff Bruce Wehling, Personal Representative of the Estate of Leonard Wehling, Jr., deceased, (hereinafter "Plaintiff" or "Wehling") is an individual who resides in Marion County, Florida. Mr. Leonard Wehling was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary fibrosis, a life-threatening and debilitating condition. In or around January 2001, he was diagnosed as suffering from atrial fibrillation ("A-fib"), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a "rhythm medication," which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced acute pulmonary

fibrosis, a serious and potentially deadly lung disease. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around January 2001, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because they did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Peter Caples, Dr. Donald Wayne, and Dr. Attanti prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Peter Caples, Dr. Donald Wayne, and Dr. Attanti were victims of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Caples, Dr. Wayne, and Dr. Attanti did not receive FDA warnings from Defendants.

e) Dr. Caples, Dr. Wayne and Dr. Attanti were not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately May 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, trouble breathing, coughing, fatigue, weakness, weight loss, and pneumonia. He was presented with a diagnosis of Amiodarone-induced acute pulmonary fibrosis. Pulmonary fibrosis is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with pulmonary fibrosis is extremely poor. Pulmonary fibrosis causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing pulmonary fibrosis, Mr. Leonard Wehling was a remarkably healthy and active individual. After developing pulmonary fibrosis, he could not walk across the room and suffered frequent pneumonias. He also lost significant weight and suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced pulmonary fibrosis.

i) After developing pulmonary fibrosis, his condition deteriorated rapidly, requiring five weeks of rehab and hospitalization. He could not adequately breathe on his own, requiring breathing assistance and oxygen use. After spending over five weeks in the hospital, Leonard Wehling, Jr. succumbed to his Amiodarone-induced acute pulmonary fibrosis and respiratory failure on July 25, 2016.

150. **Plaintiff Roy Blake**

a) On personal knowledge, Plaintiff Roy Blake, Personal Representative of the Estate of Virginia Weider, deceased, (hereinafter “Plaintiff” or “Weider”) is an individual who resides in Franklin County, Ohio. Virginia Weider was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced pulmonary disease, kidney failure, and thyroid disease, all life-threatening and debilitating conditions. In or around July 2009, she was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. Her cardiologist prescribed her a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced pulmonary disease, kidney failure, and thyroid disease, all serious and potentially conditions. She received no warning from her physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around July 2009, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below,

along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant's failure to adequately communicate such warnings, Dr. Michael Meleca prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Michael Meleca was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Meleca did not receive FDA warnings from Defendant.

e) Dr. Meleca was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately November 2016, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, wheezing, abnormal kidney function, chest pain, coughing, vision loss, fatigue, weakness, abnormal thyroid function, and difficulty with exertion. She was presented with a diagnosis of Amiodarone-induced pulmonary disease, as well as kidney failure and hypothyroidism. Amiodarone-induced pulmonary disease is a debilitating chronic, progressive condition that only worsens over time. The five-year survival rate for individuals with Amiodarone-induced pulmonary disease is extremely poor. Amiodarone-induced pulmonary disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale

of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary disease, kidney failure and thyroid disease, Virginia Weider was a healthy and active individual. After developing pulmonary disease, kidney failure and thyroid disease, she struggled to exert herself and independently perform daily life activities resulting in frequent hospitalizations. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat her Amiodarone-induced pulmonary disease, kidney failure and thyroid disease.

i) After developing Amiodarone-induced pulmonary disease, kidney failure, and thyroid disease, her condition deteriorated rapidly, requiring hospitalization. She could not adequately breathe on her own, requiring breathing assistance and oxygen use. After spending several weeks in the hospital, Virginia Weider succumbed to her Amiodarone-induced injuries on October 25, 2017.

151. Plaintiff Claudia Cafferatta

a) On personal knowledge, Plaintiff Claudia Cafferatta, Personal Representative of the Estate of Jose Neme, deceased, (hereinafter “Plaintiff” or “Neme”) is an individual who resides in Fulton County, Georgia. Mr. Neme was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced acute pulmonary toxicity, interstitial lung disease and respiratory failure, all life-threatening and debilitating lung conditions. In or around April 2018, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. His cardiologist prescribed him a “rhythm medication,” which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed Amiodarone-induced acute pulmonary toxicity, interstitial lung disease, and respiratory failure, all serious and potentially deadly lung diseases. He received no warning from his physician about potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers, and promoted and sold for “off-label” use by them.

d) In or around April 2018, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Lieppe prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were a generic brand version of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Lieppe was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Lieppe did not receive FDA warnings from Defendant.

e) Dr. Lieppe was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone® or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an “off-label” use.

f) Beginning in approximately June 2018, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include shortness of breath, trouble breathing, coughing, fatigue, weakness, abnormal thyroid and liver function and respiratory failure. He was presented with a diagnosis of Amiodarone-induced pulmonary toxicity, interstitial lung disease and respiratory failure. Amiodarone-induced pulmonary toxicity and interstitial lung disease are a debilitating chronic, progressive conditions that only worsens over time. The five-year survival rate for individuals with interstitial lung disease is extremely poor. Interstitial lung disease causes the lung tissue to become damaged, scarred and thickened, making it difficult for lungs to work properly.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced pulmonary toxicity, interstitial lung disease and respiratory failure, Mr. Neme was a healthy and active individual. After developing these Amiodarone-induced injuries, he could no longer live an active lifestyle and was soon hospitalized. He often struggled to breathe, resulting in frequent hospitalizations and oxygen use. He also suffered from a litany of other health problems related to his use of Amiodarone and medications used to treat his Amiodarone-induced interstitial lung disease.

i) After developing Amiodarone-induced interstitial lung disease and respiratory failure, his condition deteriorated rapidly, requiring hospitalization. He could not adequately breathe on his own, requiring oxygen use and BiPap, multiple medications and intensive care. After spending several weeks in the hospital, Jose Neme succumbed to his Amiodarone-induced pulmonary toxicity, interstitial lung disease and respiratory failure on November 14, 2018.

152. **Plaintiffs Roger Bolin and Sherry Bolin**

a) On personal knowledge, Plaintiff Roger Bolin (hereinafter "Plaintiff" or "Bolin") is an individual who resides in Tulare County, California. He was prescribed, purchased, and

ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced vision loss and vision complications, life-altering and debilitating conditions. In or around August 2017, he was diagnosed as suffering from atrial fibrillation (“A-fib”), which is a rhythm condition of the atrial chambers of the heart. He was subsequently prescribed a “rhythm medication” by his cardiologist, which turned out to be Amiodarone. As a proximate result of his Amiodarone use, he developed vision loss and other vision complications from Amiodarone toxicity. He received no warning from his physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to him, his doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did his doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In August 2017, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Harry Lively prescribed him a course of 200mg Amiodarone tablets for treatment of his non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. He filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Lively was a victim of the long-term and successful promotional efforts of brand innovator Wyeth

as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff's decision to take it. Also, again, Dr. Lively did not receive FDA warnings from Defendant.

e) Dr. Lively was not aware that Plaintiff's use of the medication was for a dangerous "off-label" use and, as noted above, he was not in a situation of last resort as to his atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus, and his prescription was for an "off-label" use.

f) Beginning in approximately November 2017, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include vision loss, multiple vision complications, blood clots, bleeding abnormalities, abnormal heart rhythm and fatigue. He was presented with several diagnoses related to her vision loss. These visual conditions are debilitating, chronic, progressive conditions that only worsen over time and make it difficult to see and keep up with activities of daily life.

g) He was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that he became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that his injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing vision loss and multiple vision complications, he was a remarkably healthy and active individual. After developing vision loss, he could not see well and struggled to perform necessary activities of daily life, and was unable to perform his job. He also suffers from a litany of other health problems related to his use of Amiodarone.

i) Additionally, Plaintiff Sherry Bolin is the spouse of the Plaintiff Roger Bolin, and resides with her spouse, and she depended on Roger Bolin to be her primary caretaker as they enjoyed their family and life together. As a direct and proximate result of the injuries to Plaintiff

Roger Bolin, Plaintiff Sherry Bolin has in the past and will in the future suffer and incur loss of his consortium, loss of her spouse's services, the cost and expense of having medical care, attention and treatment for her spouse, the cost of travel necessary to secure said medical care, and the cost of related medical expense for him.

153. **Plaintiff Don Dellert**

a) On personal knowledge, Don Dellert, individually and as Personal Representative of the Estate of Marilyn Dellert, deceased (hereinafter "Plaintiff" or "Dellert") is an individual who resides in Sangamon County, Illinois. Mrs. Dellert was prescribed, purchased, and ingested the drug commonly referred to as Amiodarone (described more fully herein), which was manufactured, promoted, supplied and/or distributed by Defendants and as a proximate cause thereof, developed Amiodarone-induced liver toxicity and cirrhosis of the liver, life-threatening and debilitating conditions. In or around April 2013, she was diagnosed as suffering from atrial fibrillation, which is a rhythm condition of the atrial chambers of the heart. She was subsequently prescribed a "rhythm medication" by her cardiologist, which turned out to be Amiodarone. As a proximate result of her Amiodarone use, she developed Amiodarone-induced liver toxicity and cirrhosis of the liver, serious and potentially deadly lung diseases. She received no warning from her physician about these potential life-threatening complications, nor did any warnings that Amiodarone had not been approved and was not an appropriate treatment for A-fib accompany the purchase of Amiodarone.

b) At the time the Amiodarone was prescribed to her, her doctor was not aware that the FDA had not approved Amiodarone for the treatment of atrial fibrillation or that it was not safe and effective for treating non-life-threatening atrial fibrillation because of its extreme risks relative to its benefits (compared to other, less lethal drugs) for treating atrial fibrillation. Nor did her doctor receive the FDA-mandated package inserts or black box warnings, which warn physicians of the extremely dangerous, potentially life-threatening complications associated with Amiodarone.

c) Amiodarone, which is sold as AMIODARONE HYDROCHLORIDE TABLETS and other names, is manufactured and distributed by the Defendants. Plaintiff consumed

Amiodarone; more particularly the Amiodarone manufactured by Zydus and potentially other manufacturers and promoted and sold for “off-label” use by them.

d) In or around April 2013, as a result of the long-term and pervasive promotional activities of brand innovator Wyeth to an entire generation of physicians as detailed herein below, along with the continuing sales efforts of Defendants, and because he did not receive FDA warnings as a result of Defendant’s failure to adequately communicate such warnings, Dr. Richard Katholi prescribed her a course of 200mg Amiodarone tablets for treatment of her non-life-threatening atrial fibrillation. The prescriptions were versions of Amiodarone manufactured by Zydus and potentially other manufacturers. She filled the prescription and ingested the drug Amiodarone as prescribed. Dr. Katholi was a victim of the long-term and successful promotional efforts of brand innovator Wyeth as well as continued unlawful promotional and sales efforts by Defendants that failed to disclose the details and dangers of Amiodarone toxicity related to its use for treating atrial fibrillation, which would have materially affected his decision to prescribe Amiodarone to Plaintiff and Plaintiff’s decision to take it. Also, again, Dr. Katholi did not receive FDA warnings from Defendant.

e) Dr. Katholi was not aware that Plaintiff’s use of the medication was for a dangerous “off-label” use and, as noted above, Plaintiff was not in a situation of last resort as to her atrial fibrillation. Correction of atrial fibrillation was never an FDA-approved use of Cordarone®, or its bioequivalents, including the generic formulation sold by Zydus and her prescription was for an “off-label” use.

f) Beginning in approximately September 2020, Plaintiff began to experience many of the symptoms outlined in the FDA labeling, which include abdominal pain, weakness, difficulty with exertion, and liver toxicity. She was presented with a diagnosis of Amiodarone-induced liver toxicity and cirrhosis of the liver. These life-threatening injuries are debilitating chronic, progressive conditions that only worsen over time. The five-year survival rate for individuals with organ toxicity is extremely poor.

g) She was later informed and learned that these complications were allegedly attributable to the ingestion of Amiodarone. Thus, it was some time after these diagnoses that she

became aware of Defendants' role in the improper manufacture, distribution, marketing, and sale of Amiodarone and that her injuries may have been caused by the negligence or wrongful acts of Defendants.

h) Before developing Amiodarone-induced liver toxicity and cirrhosis of the liver, Plaintiff was a healthy and active individual. After developing these Amiodarone-induced injuries, she was debilitated and subsequently hospitalized. She also suffered from a litany of other health problems related to her use of Amiodarone and medications used to treat his Amiodarone-induced injuries.

i) After developing Amiodarone-induced liver toxicity and cirrhosis of the liver, her condition deteriorated rapidly, requiring hospitalization. Her condition worsened, requiring a significant amount of time in the hospital. Marilyn Dellert succumbed to her Amiodarone-induced liver toxicity and cirrhosis of the liver on October 7, 2020.

Defendants

154. Defendant Zydus Pharmaceuticals USA, Inc. ("Zydus") is a domestic business corporation with its principal place of business in Pennington, New Jersey. Defendant Zydus regularly conducts business throughout the United States and is involved in the manufacture, distribution, marketing, promotion, sale, labeling, and/or design of Amiodarone in this State and throughout the United States as detailed below.

155. The true and precise names, roles and capacities of Defendants named as DOES 1-50, inclusive, are currently unknown to Plaintiffs and, therefore, are designated and named as Defendants under fictitious names. Plaintiffs will identify their true identities and their involvement in the wrongdoing at issue if and when they become known. These corporations and entities may include other manufacturers, promoters or distributors of the products at issue.

156. Defendants' conduct described herein was undertaken or authorized by officers or managing agents who were responsible for supervision and operations decisions relating to the manufacture, marketing, promotion, sale and/or distribution of Amiodarone and the mandated Medication Guide. The described conduct of said entities, managing agents and/or individuals was therefore undertaken on behalf of or in concert with Defendants. Defendants further had advance

knowledge of the actions and conduct of said individuals whose actions and conduct were ratified, authorized, and approved by managing agents. At all times relevant hereto, Defendants were engaged in the business of designing, licensing, manufacturing, distributing, selling, promoting, marketing and/or otherwise introducing into interstate commerce, either directly or indirectly through third parties, the prescription drug Amiodarone from and throughout this State and nationwide.

157. Defendants, acting in concert along with companies such as Wyeth and other generic manufacturers of Amiodarone as well as the distributors thereof, have engaged in a calculated and coordinated campaign of silence despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of the use of Cordarone®/Amiodarone as an indicated treatment for A-fib even though Amiodarone was approved only as a drug of “last resort” for recurrent, life-threatening ventricular fibrillation/tachycardia for whom all other treatment options had failed. Defendants did so because the prospect of significant future profits outweighed their concern regarding health and safety issues, all to the significant detriment of the public and Plaintiffs. Defendants thus engaged in a conspiracy with Wyeth and other generic drug manufacturers to suppress material facts from all Plaintiffs as set forth below. But for the conspiracy between and amongst these companies and their failure to meet their joint and several obligations to warn, including ensuring a Medication Guide in compliance with FDA regulations was delivered and that Defendants also complied with their duties under state law, the Plaintiffs would not have suffered the damages and harms detailed herein. Defendants were able to be the beneficiaries of, took advantage of, the promotional efforts of Wyeth and/or other generic manufacturers of Amiodarone, both in terms of Cordarone®, Pacerone® and other bioequivalent medications, as a result of such conduct. The aforementioned acts of concealment by Defendants served to prevent Plaintiffs and their doctors from learning: (1) Amiodarone was not FDA-approved for the treatment of atrial fibrillation and that they were taking the drug on an “off-label” basis; (2) by law, Plaintiffs were supposed to receive the Medication Guide with their prescription of Amiodarone in the form required by law; and (3) that Amiodarone-induced pulmonary fibrosis and the other ailments set forth above are not extremely

rare side effects of Amiodarone use but rather sufficiently common that the FDA requires Defendants to warn physicians and users of this risk. Any statutes of limitation are tolled during the continuation of this conspiracy, which is on-going.

158. The companies identified above acted, aided, and abetted Defendants Zydus not to disclose the material facts stated herein and/or not to properly distribute the Medication Guide to the consumers who were required to receive such Guides, with such conduct authorized and/or acted on by and through its officers, employees, agents, servants, and/or representatives, including those actively engaged in the legal defense of Defendants.

159. Each reference made in this Complaint to Defendants Zydus and DOES 1-50 include their respective predecessors, successors, parents, subsidiaries, affiliates, and divisions of the corporation for the corresponding time period in any way involved in the design testing, manufacture, distribution, sale or use of Amiodarone.

JURISDICTION AND VENUE

160. Jurisdiction over Defendants is proper because they are either a corporation organized and existing or with their principal place of business located in this State and/or have purposely availed themselves of the privilege of conducting business activities in this State because they currently maintain systematic and continuous business contacts with this State, and/or based on the allegations of conspiratorial conduct and aiding and abetting as set forth throughout this Complaint. There is complete diversity between Plaintiffs and Defendants, and the amount in controversy is in excess of \$75,000 per Plaintiff.

161. Venue is proper in this District because Defendants conduct business in this District and base their operations here. Defendants' commercial activities in this District include, but are not limited to, the promotion, sale and/or distribution of Amiodarone from this State throughout the United States.

FACTUAL BACKGROUND

162. All prescription drugs require approval by the FDA before the drug may be marketed for a specific designated use. Manufacturers of new drugs must submit a new drug application (hereinafter "NDA") to the FDA. An NDA must include information about the drug's

safety and efficiency gleaned from clinical trials for a specific designated use.² It must also propose a label reflecting appropriate use, warnings, precautions, contraindications and adverse reactions.³ A drug can only be sold for its specific designated use; any other use requires manufacturers follow a specific protocol to do so.

163. For generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act in 1984. This statute amended the Food, Drug, and Cosmetic Act (hereinafter “FDCA”) and is referred to as the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments provided an “abbreviated new drug application” (hereinafter “ANDA”) procedure for generic manufacturers.⁴ Generic manufacturers are not required to repeat the clinical trials conducted by name brand manufacturers, assuming such trials were conducted.⁵ ANDAs are approved based on the initial safety profile of the name brand drug and are subject to all post-marketing events and post-sales events, including, but not limited to, collecting, tracking, and reporting adverse incident reports regarding the drug, and also are bound by the same obligations imposed on the original manufacturer in terms of complying with labeling obligations, reporting adverse events and only selling the drug for its specific authorized use.

164. Amiodarone, as the drug is commonly known, was developed in Belgium in the 1960s as a drug for treating a common heart condition known as angina. At that time, Amiodarone was released for marketing in most countries *other* than the United States.

165. In the 1970s, American physicians began obtaining Amiodarone from Canada and Europe for use in their patients with life-threatening arrhythmias who did not respond to other drugs. This activity was sanctioned by the FDA but only on a limited basis. By the mid-1980s literally tens of thousands of Americans were taking the drug without FDA approval or testing. Physicians in the United States apparently monitored the conditions of their patients more rigorously than their colleagues around the world, because they found the drug produced a bizarre

² 21 U.S.C. §355(a)-(b).

³ 21 C.F.R. §201.56.

⁴ 21 U.S.C. §355(j).

⁵ Although clinical trials were never completed by the brand manufacturer of Amiodarone, specifically for the use of Amiodarone for the treatment of A-fib.

series of side effects that other doctors seemed to have missed and that were not caught because of the lack of testing or randomized trials. After having supplied the drug for free to thousands of Americans for over five years, the FDA was essentially forced to release Amiodarone for marketing in the United States by the mid-1980s when foreign manufacturers of the drug threatened to cut off the supply to American patients.

166. In 1985, Wyeth received FDA approval⁶ to market and sell the anti-arrhythmic heart medication Cordarone® (Amiodarone hydrochloride is the generic formulation) under a special “needs” approval without the usually mandated rigorous and FDA-approved, double-blind randomized clinical trials. Although the FDA has expressly urged Wyeth and the generic manufacturers of this drug to conduct randomized clinical trials, especially if they intend to market Amiodarone for any of the other less serious arrhythmias and particularly on the targeted demographic of individuals over the age of 65, such trials have never been conducted. The FDA approval for Cordarone® thus remains a special and unusual “special needs” approval, as the customary and rigorous randomized clinical trials now required by the FDA for all new drug applications have never been conducted for Amiodarone. Wyeth was the initial manufacturer, promoter and distributor or “brand manufacturer” of Cordarone® in the United States, upon whose efforts the generic manufacturers, including Zydus, piggybacked in terms of any testing (or lack thereof), warnings, and/or promotion of the drug.

167. Wyeth’s Cordarone® was approved by the FDA only as a drug of last resort for patients suffering from documented, recurrent, life-threatening, ventricular fibrillation and ventricular tachycardia when these conditions would not respond to other available anti-arrhythmic drugs and therapies. In essence, it was approved only for use in individuals facing probable death as their last hope for an efficacious treatment. It was never approved, even on a special needs basis, for the treatment of atrial fibrillation that Plaintiffs suffered from, as detailed above. In addition, the FDA required any person who was prescribed this medication was to first directly receive a

⁶ See NDA 18-972, Approval Letter, December 24, 1985.

“Medication Guide.”⁷ Distributing this Medication Guide to consumers was and is the responsibility of Defendants, not of any physician.

168. Wyeth and others, including several generic manufacturers, aggressively and successfully marketed Cordarone® or its later initial bioequivalent Pacerone® for inappropriate “off-label” uses as a “first line anti-arrhythmic therapy.” Beginning in the late 1980s until the FDA warned and then ordered them to stop doing so as set forth below, Wyeth instituted and maintained an aggressive marketing plan positioning Amiodarone as a “first line anti-arrhythmic” via peer to peer events, articles in scholarly journals, and materials presented to physicians. These campaigns in many situations focused on the use of the drug for atrial fibrillation, even though such general use was not approved by the FDA, and failed to warn prescribing physicians of the potential dangers associated with Amiodarone toxicity and dangers to atrial fibrillation patients through FDA warnings. Wyeth’s campaigns were so pervasive and effective that for an entire generation of physicians and in on-line forums that consumers reference as set forth above, the drug wrongfully became a first line therapy for atrial fibrillation because physicians and consumers were not warned of many of the potential dangers of the drug or that it had never been approved for such use by the FDA. Wyeth’s fraudulent and misleading marketing campaigns resulted in repeated warning letters from the FDA to stop the false and misleading promotion of the drug, where such promotion downplayed the risks and promoted the drug as a first line anti-arrhythmic therapy.⁸ The FDA letters noted that it is unlawful for a manufacturer to promote any drug for a use not described in the approved labeling of the drug.⁹ The purpose of this federal requirement is to protect patients by ensuring drug manufacturers test prospective uses of their drugs to randomized and well-controlled clinical trials to determine whether the drug is safe and effective for such specific designated uses. These requirements are meant to ensure that drug companies would give physicians and medical personnel trustworthy information so that medications are appropriately prescribed. That was not the case for Amiodarone and its use for the treatment of A-

⁷ Medication Guide for Amiodarone HCI. <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf>

⁸ Warnings by the FDA to Wyeth began as early as 1988. <http://www.mcclatchydc.com/2003/11/04/28118/fda-overight-of-off-label-drug.html>

⁹ See 21 U.S.C. §§331(d), 352(f), and 355.

fib. Any specifically prescribed uses beyond those approved by the FDA are deemed “off-label” because they have not been approved by the FDA. While a pharmaceutical company is permitted to disseminate certain information about off-label uses, such dissemination must adhere to strict requirements. The manufacturer must submit an application to the FDA seeking approval of the drug for off-label use; the manufacturer must provide its marketing materials to the FDA before dissemination; the materials must be in unabridged form; and the manufacturer must include disclosures that the materials pertain to an unapproved use of the drug, and, if the FDA deems it appropriate, “additional objective and scientifically sound information . . . necessary to provide objectivity and balance.”¹⁰ Neither Wyeth nor the Defendants such as Zydus who were generic manufacturers and thus the beneficiaries of these promotional efforts, fully did so. This law also requires pharmaceutical companies to furnish federal regulators with advance copies of the information they disseminate.¹¹ Any deviation from these requirements violates FDA regulations. The dissemination of information in violation of these provisions also violates the FDCA.¹² Defendants took advantage of Wyeth's marketing plan positioning Amiodarone as a “first line anti-arrhythmic” described above, and directly benefited from the decades of marketing of the drug for “off-label” uses by Wyeth. The generic version of Amiodarone manufactured by Zydus are also subject to the same advertising, marketing, and promotional requirements and restrictions set forth by the FDA for Wyeth in their advertising, marketing, and promotion of the drug Cordarone®. Defendants were able to take advantage of these promotional efforts in their sales of Amiodarone, focusing primarily on pricing in their marketing and promotional efforts to increase market share.

169. In connection with Defendants' unlawful promotion and/or sale of Amiodarone not only as a treatment for atrial fibrillation, but also as a first-line treatment, they either directly or indirectly provided the indications and usage information regarding Amiodarone to the distributor of the Physician's Desk Reference (“PDR”) and the developer of Epocrates, the two most widely used reference materials used by physicians in prescribing situations. However, Defendant did not

¹⁰ 21 U.S.C. §360aaa, *et seq.*

¹¹ 21 U.S.C. §360aaa.

¹² 21 U.S.C. §331(z).

provide the FDA warnings for generic amiodarone for publication in the physical PDR any time after 2007.

170. The PDR is an annual publication compiling product information about pharmaceuticals. Each year the PDR and its supplements are sent free of charge to licensed physicians in the United States and abroad. A typical entry includes the trade name and chemical name of the drug, a description of the drug, indications and contraindications for its use, warnings, adverse reactions, administration and dosage, and information on managing and adjusting the dosage of the drug. Likewise, Epocrates is a prescription drug reference source available online and via an application usable on smartphones and tablets, which likewise provides physicians with information about prescription drugs including uses, warnings, contraindications, dosage, etc. However, Epocrates provides this information for both brand name and generic drugs.

171. For many years, physicians relied upon the PDR book in prescribing situations to provide them with information about drugs available to treat certain conditions, indications and usages for drugs, as well as dosage information and contraindications. However, since at least 2010, the majority of physicians in the United States use the Epocrates application, which calls itself “[t]he #1 medical reference app,” in prescribing situations. The application, which is accessible on a smartphone or tablet, provides the prescribing physician with the same information about a particular condition or drug as the PDR. A 2014 article from *The New England Journal of Medicine* revealed that Epocrates tracks individual physicians’ search patterns, which are then used to send targeted “DocAlerts,” most of which are industry sponsored, which appear on the physicians’ tablet or smartphone screen within the application. Epocrates admits DocAlert is a marketing tool for pharmaceutical companies, noting “DocAlert messaging is an excellent way for pharmaceutical brand managers to target physicians at the point of care, by specialty.”

172. According to these reference materials, the information about prescription drugs that appears in Epocrates and the PDR comes from the manufacturers of the drug(s) as well as the FDA. The information is also supposed to be approved by the FDA. However, both the PDR and Epocrates contain misleading and incomplete information about Amiodarone, which deceives physicians into believing Amiodarone: (1) is approved for the treatment of A-fib when it never

was; (2) was not approved solely as a drug of “last resort” for patients with ventrical fibrillation (“V-fib”) facing death; (3) provides benefits to A-fib sufferers that outweigh the safety risks; and/or (4) underwent appropriate FDA-approved randomized, clinical trials, which it never did.

173. Defendants and other generic manufacturers of Amiodarone also are aware of the use of various other methods to unlawfully promote Amiodarone for unapproved uses including the use of Electronic Health Record companies such as Cerner, AthenaHealth, Epic, AllScripts, Practice Fusion and NextGen Healthcare, which provide generic manufacturers of Amiodarone a platform to reach physicians at the point of care in an attempt to promote Amiodarone and influence prescribing behavior.

174. Generic drug manufacturers also use a variety of internet-based tools to exert prescribing influence over physicians. This includes social networks specifically for healthcare providers like Sermo and Doximity where doctors can learn about new medical news and connect with other physicians. It also includes the creation of sponsored discussion forums to target doctors and identify key opinion leaders that can then be used to influence other physician’s prescribing habits. These forums are used to solicit physician’s opinions through surveys (paid and voluntary), recruitment of physicians for focus-groups.

175. Manufacturers of Amiodarone also provide false and/or misleading information to various reference sources used by physicians when contemplating prescribing a drug for an off-label use. This includes Wolters Kluwer’s publications and applications, *Drug Facts and Comparisons* and *Off-Label Drug Facts*, which reports Amiodarone is an appropriate treatment for A-fib. As evidence of the success of this marketing and promotional campaign that Defendants were able to take advantage of and did nothing to correct, information about the use of Amiodarone as a treatment for A-fib has also been reported in a variety of sites used and visited by consumers, such as Web MD, the Mayo Clinic and even the American Heart Association, as well as retailer websites such as Wal-Mart.

176. Although people commonly understand a drug’s “label” to refer to the sticker affixed to a prescription bottle, in this context the term “label” refers more broadly to the written material that is sent to or accessed by the physician who prescribes the drug and the written

material that comes or is supposed to come with the prescription bottle when the drug is handed to the patient at the pharmacy, such as the Medication Guide. 21 U.S.C. §321(m). These inserts contain detailed information about the drug's medical uses and health risks. 21 U.S.C. §355(b)(1)(F); 21 C.F.R. §201.57(a). Thus, the information about a particular drug in Epocrates or the PDR is also considered "labeling" under 21 U.S.C. §321(m) and as such cannot be false or misleading. The indications and usages of Amiodarone in both Epocrates and the PDR show the treatment of atrial fibrillation as an indicated use the drug, which is false and misleading as it has never been approved by the FDA for the treatment of atrial fibrillation. Zydus licensed pictures of its Amiodarone pills to Epocrates for public display on the paid version of the application, failed to prohibit Epocrates from posting pictures of its pills on the Epocrates application or website and/or permitted such use.¹³ Prescribing physicians were thus not adequately warned, because they received misleading "warnings" or information in addition to the FDA-approved labeling that watered down the FDA-approved labeling and rendered the overall warnings inadequate. Defendants themselves did not provide the FDA labeling to Plaintiffs' physicians. Because of this, the physicians were forced to rely on misleading third-party information as described above. Because of Defendants' failure to adequately communicate FDA labeling, the prescribing physicians identified above did not know that Amiodarone was not safe to prescribe for A-fib. Defendants thus did not take the steps reasonably necessary to bring that knowledge to the attention of the medical profession.

177. Defendant Zydus, seeking to capitalize and being the beneficiary of the off-label marketing campaign initiated by Wyeth, received approval for the manufacture, marketing, sale and distribution of the generic formulation of Amiodarone.¹⁴ As it relied on the FDA filings of Wyeth, Zydus would have sought and only obtained approval to market Amiodarone only as a drug of last resort for the treatment of life-threatening, recurring ventricular fibrillation or tachycardia when other treatment options had failed, when it either knew or should have known

¹³ <https://online.epocrates.com/drugs/13409/amiadarone/Pill-Pictures>.

¹⁴ http://www.accessdata.fda.gov/drugsatfda_docs/appletter/1998/74739ltr.pdf

that more than four out of every five Amiodarone prescriptions were for unapproved uses. As with all generic bioequivalent approvals, Defendants were required by the FDA to provide patients prescribed the drug with all FDA-approved labels, warnings and additionally, Medication Guides, as required from the brand formulation manufacturer, Wyeth, and as updated as directed by the FDA.¹⁵

178. Correction or treatment of atrial fibrillation was never an FDA-approved use of Cordarone® or Amiodarone, either on a special needs basis or otherwise.¹⁶ Before being prescribed Amiodarone, each of the Plaintiffs who ingested Amiodarone were diagnosed with atrial fibrillation not deemed life threatening. None of these Plaintiffs were in a medical situation of “last resort” as to the management of their ventricular tachycardia, which was the only approved use of Amiodarone.

179. This off-label prescription and distribution of the drug to control a non-life threatening atrial fibrillation, which also is a direct result of the long-term promotional efforts of Wyeth and the continuing sales efforts of Defendants, and without the required Medication Guide, was a producing and proximate cause of Plaintiffs’ injuries.

180. The most serious side effect of Amiodarone, and the focus of the FDA labeling, is pulmonary toxicity/lung disease. Amiodarone produces two types of lung disease. The first is acute pulmonary syndrome, which looks and acts like typical pneumonia, with a sudden onset of cough and shortness of breath, a condition that improves once Amiodarone is stopped. The second type is more dangerous and life-threatening. This condition involves a gradual, almost unnoticeable, stiffening of the lungs that both the doctor and patient can overlook until finally severe irreversible lung damage has been done. This condition can occur quickly after taking the drug or can occur years after taking the drug. Lung toxicity has been found by the FDA to be in approximately 17%, or 1 in 5, patients taking the drug. Fatalities from pulmonary toxicity have been routinely reported to both Wyeth and other generic drug manufacturers, including Zydus, that were not fully reported to the FDA, thus making them knowing participants in the conspiracy or concerted action to

¹⁵ See 21 U.S.C. §355(j)(2)(A)(v); §355(j)(4)(G).

¹⁶ See Application 75-188 Approval Letter to Robert A. Fermia dated February 24, 1999.

mislead users and/or prescribers of this drug. Because Plaintiffs' physicians were not provided all FDA warnings, they did not know, for example, that Amiodarone "should only be used in adults with life-threatening heartbeat problems called ventricular arrhythmias" and even then when "other treatments did not work or were not tolerated."¹⁷ Plaintiffs did not know that any other use such as the use for supposed treatment of their A-fib was considered to be "off-label" and not approved by the FDA, or of the corresponding dangers associated with such uses.

181. Plaintiffs' physicians did not know "the medicine stays in your body for months after treatment is stopped."¹⁸ The effects of Amiodarone are extremely long lasting. Amiodarone is fat-soluble, and tends to concentrate in tissues including fat, muscle, liver, lungs, and skin. It confers a high volume of distribution and a long half-life (the amount of time it takes for one-half of an administered drug to be lost through biological processes such as metabolism and elimination). Amiodarone has also been determined to affect many different organs in many ways. First, the drug takes many weeks to achieve the maximum effectiveness. Amiodarone is literally "stored" in most of the tissues of the body and as a result, to "load" the body with the drug all the tissues need to be saturated. Therefore, the typical loading regimen of Amiodarone is to use extremely large dosages of the drug for the first week to two weeks, then to taper the dosage over the next month. It is not unusual to give a patient 1200 to 1600 mg a day when starting the drug and to maintain the patient on 100 to 200 mg per day on a chronic basis. Amiodarone also leaves the body very slowly. The drug is not excreted like most drugs through the liver or kidney but is only lost when Amiodarone-containing cells such as skin cells or cells from the GI tract are lost. Therefore, even when it is decided that the patient needs to stop taking Amiodarone the drug remains in the system in measurable quantities for months and even years.

182. Because the drug is stored in many different types of tissues it can cause side effects that affect many different types of organs. And because of its long half-life, Amiodarone's dangerous properties continue to cause injuries in patients such as Plaintiffs long after they ceased

¹⁷ Medication Guide for Amiodarone HCI. <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf>.

¹⁸ Medication Guide for Amiodarone HCI. <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM152841.pdf>.

using the drug, and even after they have been diagnosed with particular issues, including serious pulmonary injuries. Thus, a Plaintiff could be diagnosed with pulmonary issues but not be aware it is associated with Amiodarone use for months if not years after that diagnosis. This information was unknown to Plaintiffs due to the failure of the Defendants to provide the Medication Guide and otherwise provide adequate warnings to Plaintiffs, an illegal act that has been continuous and on-going.

Plaintiffs' Use of Amiodarone and Resulting Injuries

183. As a result of Defendants' illegal, off-label promotion and distribution of Amiodarone as a viable treatment for atrial fibrillation without the required Medication Guide and without communicating other FDA warnings to doctors, Plaintiffs' physicians were unaware of the extent to which Plaintiffs would be exposed to the risks of pulmonary fibrosis and other injuries.

184. As a result of the information concealed by Defendants and the half-life of Amiodarone as set forth above, the link between Plaintiffs' injuries and Defendants' wrongful conduct was not discovered, and through reasonable care and due diligence could not have been discovered, until a date within the applicable statutes of limitation for filing Plaintiffs' claims. Even a diagnosis of pulmonary toxicity would not necessarily lead someone to believe it was due to the use of Amiodarone, particularly because of the parallels between that diagnosis and pneumonia.

185. A lay person exercising reasonable diligence could not have discovered, among other things, that (1) Amiodarone was not FDA-approved for the treatment of atrial fibrillation and they took the drug on an "off-label" basis; (2) by law he or she was supposed to receive the Medication Guide with the prescription of Amiodarone; and (3) that Amiodarone-induced pulmonary fibrosis is not an extremely rare side effect of Amiodarone use but rather sufficiently common that the FDA requires Defendants to warn physicians and users of this risk. Such a discovery would require a complex examination and analysis of various legal statutes and regulations, which is far beyond the knowledge or ability of a lay person.

186. For the reasons detailed below, the running of any applicable statute of limitations is also tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to their conspiracy with companies such as Wyeth to conceal the true facts detailed herein through the use of affirmative misrepresentations and omissions of material fact from Plaintiffs and Plaintiffs' physicians of the true risks associated with Amiodarone and the failure to ensure distribution of the Medication Guides in the form and manner required by law.

187. At all materials times, despite FDA warnings and thousands of adverse patient experiences, Defendants continued their marketing, promotional, and sales practices beginning from at least 1999 as set forth above through the present date, and have continued in their acts of conspiracy as detailed above. Thus, despite the repeated changing of the warnings and labeling multiple times over the past 25 years and the requirement for the distribution of FDA warnings to all patients as set forth below, and knowing of numerous catastrophic injuries caused by both Cordarone® and Amiodarone, Defendants continued to actively conceal and understate the drug's nature and adverse risks of catastrophic injury, pulmonary injury and death despite their duty to disclose such information and the need to distribute and ensure distribution of FDA warnings, thereby tolling any applicable statutes of limitations.

FIRST CAUSE OF ACTION¹⁹

(Strict Products Liability – Failure to Warn under the New Jersey Products Liability Act)

188. Plaintiffs incorporate by reference all preceding paragraphs of this Complaint, as though set forth in their entirety in this cause of action and further allege as follows.

189. At all times relevant to this action, Defendants engaged in the business of designing, manufacturing, testing, marketing, labeling, causing to be distributed and/or otherwise placing into the stream of commerce Amiodarone for sale to, and use by, members of the public, including Plaintiffs who took the drug.

¹⁹ Plaintiffs expressly reserve for appeal their theories and causes of action dismissed by the district court.

190. Under the New Jersey Products Liability Act, Defendant has a duty to communicate FDA warnings to prescribers. Amiodarone posed increased risks of harm and side effects that were known or knowable to Defendants by the use of scientific knowledge available before, at and after the time of the manufacture, distribution, and sale of Amiodarone. Defendants knew or should have known of the defective condition, characteristics, and risks associated with said product, for the reasons set forth herein. Defendants disregarded this increased risk of harm by failing to adequately warn of such risks; unlawfully concealing the dangerous problems associated with increased risk of harm by failing to provide FDA warnings to Plaintiffs' physicians.

191. The Amiodarone that was manufactured, distributed, and/or sold by Defendants to Plaintiffs was in a defective condition that was unreasonably and substantially dangerous to any users or ordinary consumers of the device, such as Plaintiffs. Such ordinary consumers, including Plaintiffs, would not and could not have recognized or discovered the potential risks and side effects of Amiodarone as set forth herein based on the lack of information provided to them that Defendants were required to ensure they directly received.

192. The warnings and directions provided with Amiodarone by Defendants failed to adequately warn of the potential risks and side effects of Amiodarone and the dangerous propensities of this medication, which risks were known or were reasonably scientifically knowable to Defendants, when they failed to provide proper warnings. Specifically, Defendants failed to communicate FDA warnings to Plaintiffs' physicians.

193. Defendants' failure to provide FDA warnings to Plaintiffs' prescribing physicians was a substantial factor in causing Plaintiffs' injuries, losses and damages, as described herein. Further, the prescribing physicians read and relied on the PDR, Epocrates app or other prescribing reference source in prescribing Amiodarone to Plaintiffs. Zydus either was or should have been aware of the statements made in those materials since, for example, Zydus permitted use of pictures of their own Amiodarone pills on the Epocrates app and were under a duty to correct these materials as a form of labelling. If the information contained in the PDR, Epocrates or other reference sources had been truthful and not concealed material information or if Defendants had

adequately communicated the FDA warnings to Plaintiffs' physicians, the prescribing physicians would not have prescribed Amiodarone to treat Plaintiffs' A-fib.

194. Prescribing physicians were not adequately warned, because, in the absence of FDA warnings provided by Defendants, they received misleading "warnings" or information from third parties in addition to the FDA-approved labeling that watered down the FDA-approved labeling and rendered the overall information provided inadequate. Prescribing physicians did not know that Amiodarone was not safe to prescribe for the treatment of A-fib.

195. Defendants' Amiodarone were expected to and did reach Plaintiffs and their physicians and pharmacists without substantial change in their condition as manufactured, caused to be distributed, and sold by Defendants. Additionally, Plaintiffs' physicians prescribed, and Plaintiffs used, Amiodarone in the manner in which Amiodarone was intended to be used by Defendants, making such use reasonably foreseeable to Defendants.

196. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental anguish, economic losses and other damages. As a direct and proximate result, Plaintiffs expended money and will continue to expend money for medical bills and expenses. Plaintiffs are entitled to compensatory, special and other damages in an amount to be proven at trial.

SECOND CAUSE OF ACTION

(Negligence – Failure to Warn)

197. Plaintiffs hereby incorporate by reference all previous paragraphs, as though set forth in their entirety in this cause of action and further allege as follows.

198. At all relevant times, Defendants, and each of them, engaged in the business of designing, manufacturing, testing, marketing, labeling, causing to be distributed and/or placing into the stream of commerce Amiodarone for sale to, and use by, members of the public, including the Plaintiffs who took the drug.

199. In the alternative to the above cause of action, assuming this Court holds that the law of Plaintiffs' home states applies, Defendant had a duty under the law of Plaintiffs' home states to communicate FDA warnings to prescribers. Amiodarone posed increased risks of harm and side

effects that were known or knowable to Defendants by the use of scientific knowledge available before, at and after the time of manufacture, distribution, and sale of Amiodarone. Defendants knew or should have known of the defective condition, characteristics, and risks associated with said product, as previously set forth herein. Defendants disregarded this increased risk of harm by failing to reasonably ensure that Plaintiffs' physicians received FDA labeling.

200. The Amiodarone ingested by Plaintiffs were expected to and did reach Plaintiffs and their physicians and pharmacists without substantial change in their condition as manufactured, caused to be distributed, and/or sold by Defendants. Additionally, Plaintiffs used Amiodarone in the manner in which Amiodarone was intended to be used by Defendants, making such use reasonably foreseeable to Defendants.

201. Further, the prescribing physicians read and relied on the PDR, Epocrates app or other prescribing reference source in prescribing Amiodarone to Plaintiffs. Zydus either was or should have been aware of the statements made in those materials since, for example, Zydus permitted use of pictures of their own Amiodarone pills on the Epocrates app and were under a duty to correct these materials as a form of labelling. If the information contained in the PDR, Epocrates or other reference sources had been truthful and not concealed material information, the prescribing physicians would not have prescribed Amiodarone to treat Plaintiffs' A-fib.

202. Prescribing physicians were not adequately warned, because, instead of receiving unadulterated FDA warnings from Defendants, they received misleading "warnings" or information from third parties in addition to the FDA-approved labeling that watered down the FDA-approved labeling and rendered the overall warning inadequate. Prescribing physicians did not know that Amiodarone was not safe to prescribe for A-fib. Defendants, thus, did not take the steps reasonably necessary to bring that knowledge to the attention of the medical profession.

203. As a direct and proximate result of Defendants' manufacture, promotion, distribution, and/or sale of Amiodarone, Plaintiffs suffered the injuries, losses and damages herein described.

204. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs have sustained and will continue to sustain severe physical injuries, severe emotional distress, mental

anguish, economic losses and other damages. As a direct and proximate result, Plaintiffs expended money and will continue to expend money for medical bills and expenses. Plaintiffs are entitled to compensatory, special and other damages in an amount to be proven at trial.

THIRD CAUSE OF ACTION

(Wrongful Death)

(Against All Defendants by the Decedent Plaintiffs)

205. The “Decedent Plaintiffs” (Plaintiffs Christine Jankowski, Mary Blevins, Tiffany Brooks, Sonja Butler, JoAnn Collings, Vernon DeBoard, Susan Fedorsha, Andrew Fancher, Ruth Glascoe, Barbara Grantham, Carolyn Hale, Henry Henson, Sara Huff, Michael Johnson, Stephanie Kibodeaux, Mark Laganelli, Nancy Lovvorn, Kim Lee Lowe, Brenda Medler, Karen Roth, Albert Shepherd, Doyle Turner, Janice Upton, Jacqueline Fabbri, Carletta Williams, Darlene Glasgow, Bill Worthington, Veronica Itano, Amy Miller, Doris Lyle, Brenda Barefoot, Theresa Graves, Harsharan Sandhu, Patricia Sopp, Barbara Clark, Debra Lister, Raymond Wright, Jacqlyn Carter, Carla Ellis, Nancy Barber, Loyce Parr, Patricia Rhodes, James Thomas, Diana Cutright, Andrea Miller, Diane Desmond, Bruce Wehling, Roy Blake, and Claudia Cafferatta) incorporate by reference all preceding paragraphs of this Complaint, as though set forth in their entirety in this cause of action and further allege as follows.

206. The Decedent Plaintiffs are the surviving heirs of the persons listed above who used Defendants’ Amiodarone products and died as a proximate result (“Decedents”). Said Decedents were prescribed, supplied with, received and ingested Amiodarone that was placed in the stream of commerce by Defendants.

207. The injuries and death of Decedents was caused by the wrong acts, omissions and misrepresentations of Defendants as set forth above.

208. As a result of the conduct of Defendants and their ingestion of Amiodarone, the Decedents suffered fatal injuries.

209. As a result of the deaths of their relatives, the Decedent Plaintiffs were also deprived of the love, companionship, comfort, support, affection, society, solace and moral support of these Decedents.

210. The Decedent Plaintiffs are entitled to recover economic and non-economic damages against all Defendants for wrongful death directly and legally caused by the wrongful acts, omissions and misrepresentations of Defendants.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against the Defendants as follows, as appropriate and applicable for the particular causes of action set forth above:

1. For general (non-economic) and exemplary damages proportionate thereto according to proof at the time of trial;
2. For special (economic) and exemplary damages proportionate thereto according to proof at the time of trial;
3. For restitution and restitutionary disgorgement of all revenues or profits that Defendants have obtained through design, promotion, marketing, manufacture, distribution and/or sale of Amiodarone;
4. For pre-judgment and post-judgment interest as permitted by law;
5. For costs of suit incurred herein as permitted by law, including attorneys' fees pursuant to the claims that expressly or relatedly permit such an award;
6. For injunctive relief including, but not limited to, prohibiting Defendants from selling Amiodarone without also distributing the Medication Guide in the manner required by law;
7. For such other and further relief as this Court may deem proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all claims so triable.

DATED: June 21, 2021

/s/ *Anthony Pinnie* _____
Anthony Pinnie
Pinnie Law Offices
334 West Front Street
Media, PA 19063
Telephone: (610)-892-9200
Email: apinnie@pinnielaw.com

CONSUMER LAW GROUP OF CALIFORNIA
Alan M. Mansfield (SBN 125998)
alan@clgca.com
16870 W. Bernardo Dr. Suite 400
San Diego, CA 92127
Tel: (619) 308-5034
Fax: (855) 274-1888

DOYLE APC
Chris W. Cantrell (SBN 290874)
chris@doyleapc.com
550 West B Street
Fourth Floor
Tel: (619) 736-0000
Fax: (619) 736-1111

WOOD LAW FIRM
E. Kirk Wood (To Apply *Pro Hac Vice*)
ekirkwood1@cs.com
P. O. Box 382434
Birmingham, AL 35238
Tel: (205) 612-0243

Johnson English Law Center
12222 Merit Drive, Suite 1200
Dallas, Texas 75251
M: 214.528.4300 / F: 972-733-1335
jenglish@englishpllc.com

WILLIAMS ATTORNEYS PLLC
Nathaniel J. Clark
Associate Attorney
500 N. Water St. Ste 500
500 Corpus Christi, TX 78401
Office: 361-885-0184

Jack E. Urquhart
Of Counsel
The Snapka Law Firm
P.O. Drawer 23017
Corpus Christi, Texas 78403
(361) 888 7676

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that I have this 21st day of June, 2021, electronically filed and/or mailed a copy of the foregoing to the following:

Kateryna Stupnevich, Esq.
Arthur J. Liederman, Esq.
Nicole M. Battisti, Esq.
Morrison Mahoney, LLP
Wall Street Plaza
88 Pine Street, Suite 1900
New York, NY 10005
Telephone: 212-825-1212
Facsimile: 212-576-8934
kstupnevich@morrisonmahoney.com
alielman@morrisonmahoney.com
nbattisti@morrisonmahoney.com

/s/ Anthony Pinnie
Anthony Pinnie